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INVESTIGATION OF HEW

REPORT

OF THE

SPECIAL SUBCOMMITTEE ON INVESTIGATION OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

Pursuant to Section 136 of the Legislative Reorganization Act of 1946, Public Law 601, 79th Congress, and House Resolution 35, 89th Congress

OCTOBER 13, 1966.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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89TH CONGRESS, 2d Session } HOUSE OF REPRESENTATIVES { REPORT No. 2266

STUDY OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OCTOBER 13, 1966.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[Pursuant to sec. 136 of the Legislative Reorganization Act of 1946, Public Law 601, 79th Cong., and H. Res. 35, 89th Cong.]

The Committee on Interstate and Foreign Commerce herewith submits for the information of the House of Representatives, a report of its Special Subcommittee on Investigation of the Department of Health, Education, and Welfare, relating to the subcommittee's activities and making certain recommendations regarding that Department.

The committee, by section 136 of the Legislative Reorganization Act is charged with the duty of "exercising continuous watchfulness of the execution by the administrative agencies concerned of any laws, the subject matter of which is within the jurisdiction of the committee" and by House Resolution 35, 89th Congress, the committee, acting as a whole or by a subcommittee, is authorized to make investigations and studies into matters within its jurisdiction, including the administration of the statutes which certain specified agencies administer.

In April of last year, following an examination which the committee's Subcommittee on Public Health and Safety had made of the organization of the Public Health Service in the 88th Congress, and the report to the President by a panel, headed by Dean E. Wooldridge, on the organization and activities of the National Institutes of Health, the committee established within its Subcommittee on Investigations a Special Subcommittee on the Organization and Structure of the Department of Health, Education, and Welfare, as it pertains to public health, especially the Public Health Service, including the National Institutes of Health, and the Food and Drug Administration.

The membership of the subcommittee appointed April 14, 1965, comprised: Paul G. Rogers, chairman, Lionel Van Deerlin, Oliva Huot, J. Arthur Younger, and Willard S. Curtin. Messrs. John J. Gilligan and Ancher Nelsen were added to the subcommittee at the start of the session in 1966.

This special subcommittee, under the able direction of its Chairman Paul G. Rogers, has completed a report which the committee is submitting herewith. This report contains a great amount of very valuable information and a number of recommendations by the subcommittee on the organizational structure of the Department. The committee believes that the timeliness of the subcommittee report warrants this transmission to the House for the benefit of the Members and of the public.

LETTER OF TRANSMITTAL

OCTOBER 5, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

MY DEAR MR. CHAIRMAN: I have the honor to present herewith, for transmittal to the House of Representatives, a report of the Special Subcommittee on Investigation of the Department of Health, Education, and Welfare, submitted pursuant to the request made by the former chairman, Hon. Oren Harris, on April 14, 1965.

Sincerely yours,

PAUL G. ROGERS,
Chairman, Special Subcommittee on Investigation of the Department of Health, Education, and Welfare.

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BACKGROUND—THE SPECIAL SUBCOMMITTEE ON INVESTIGATION OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Background—The Special Subcommittee on Investigation of the Department of Health, Education, and Welfare

On April 14, 1965, Chairman Oren Harris of the House Committee on Interstate and Foreign Commerce, ordered an investigation of the organizational structure of the Department of Health, Education, and Welfare as it pertains to matters of public health. A special subcommittee was formed to make this study under the chairmanship of Congressman Paul G. Rogers of Florida. Chairman Staggers, who took over the chairmanship of the Commerce Committee in January of this year, reemphasized the need for this study. The present document is the result of more than a year of study into various aspects of the Department.

Pursuant to paragraph 11 of rule XI of the Rules of the House of Representatives, the Committee on Interstate and Foreign Commerce has legislative jurisdiction over the subjects of public health and quarantine. In this study, emphasis has been placed on those agencies and bodies within HEW whose activities are within the jurisdictional purview of the Interstate and Foreign Commerce Committee.

In its inquiry the subcommittee has focused primarily on the programs and organizational structures of HEW which have a direct bearing on the provision of health services. Solution to the long-standing organizational and administrative problems in this area should have far-reaching consequences in the improvement of the Nation's health.

The present leadership of the Department has shown itself to be aware of many of these problems and concerned with their solution. During the course of this subcommittee's study of HEW, one of the most significant developments has been an almost complete change-over in the top leadership of the Department. This has been accompanied by a willingness on the part of the Department to engage in a constructive self-criticism and reevaluation of existing programs and organizational patterns. Along with this, the subcommittee has noted a rising level of initiative within the Department which gives rise to the hope that effective attacks will be mounted against the problems discussed in this report.

These encouraging signs should not, however, obscure the fact that serious problems beset the Department, and the Federal health effort in general. Solutions cannot be expected overnight. The subcommittee has deemed its assignment to be one of pinpointing and defining the major problem areas. The solutions to these problems must not be long delayed if the Nation's commitment to better health for all citizens is to be realized.

The subcommittee has made use of a number of sources of information, including a program of informal interviews and meetings with Department personnel from various levels. Secretary Gardner and former Secretaries Celebrezze and Folsom have met with members of the subcommittee. The subcommittee has undertaken a review of departmental publications and policy statements, interorganiza-

tional relationships between various segments of the Department, research grant awarding operations, and scientific information dissemination activities.

In addition, comments and opinions from scientific and lay authorities were obtained through interviews and interim correspondence. The Governors of all 50 States were requested to furnish their recommendations and observations on the current status of the Federal-State-local relationship in matters of public health and health-related research. Widespread interest, and concern, with respect to this subject matter was evidenced by the large response to these letters, both from the Governors of the various States and from interested State health authorities.

The subcommittee's study involved three phases: (1) Preliminary survey; (2) detailed study; and (3) public hearings.

(1) The preliminary survey:

At the request of the subcommittee, several background documents were prepared by the Department of HEW, in collaboration with the subcommittee staff, to provide basic reference information concerning the organization and functions of the various agencies and bureaus within the Department. These documents include the following:

(*a*) "The Department of Health, Education, and Welfare—Background Material Concerning the Mission and Organization of the Health Activities of the Department," 589 pages, in 2 volumes.

(*b*) "Compilation of Selected Public Health Laws," 2 volumes; 519 pages.

At the request of the subcommittee, the Bureau of the Budget submitted the following background paper:

(*c*) "A Report of Federal Health Programs Carried Out by Agencies other than the Department of Health, Education, and Welfare." (This report contains a section listing the major interagency committees related to health activities, and reflects a part of the effort made by Federal agencies to coordinate their health activities. See appendix A, this report.)

(2) Detailed study:

The subcommittee directed letters to the Governors of all 50 States, and, by reference, their respective health authorities. The replies to this correspondence were analyzed by the subcommittee to select the specific operations of the Department for further, more intensive inquiry. (Selected portions of this correspondence are included in the printed transcript of the subcommittee hearings, as apps. I and II thereof.)

In addition, numerous staff interviews and informal subcommittee meetings with various officials from the Department were conducted. The results of this research, summarized in approximately 60 working papers by the subcommittee staff, were the basis for structuring the subcommittee hearings.

(3) Hearings:

The subcommittee commenced hearings during the week of April 18–22, 1966. During the first 3 days of these hearings, the subcommittee heard the testimony of a distinguished group of witnesses representing all levels of State and local government, as well as the academic world. The subcommittee was impressed with the obvious dedication of the witnesses who appeared before it, their experience

in the area of public health, and the deep concern they expressed regarding the present difficulties which impair the efficient utilization of the Nation's health resources.

The witnesses appearing before the subcommittee during the initial 3 days of hearings were:

Dr. Henrik Blum, county health officer, Contra Costa County, Calif.
Dr. Bernard Bucove, president, Association of State & Territorial Health Officers, and director, Washington State Department of Health.
Dr. Joseph E Cannon, director, Department of Health, State of Rhode Island.
Hon. John H. Chafee, Governor of the State of Rhode Island.
Margaret B. Dolan, R.N., M.A., professor and head, Department of Public Health Nursing, School of Public Health, University of North Carolina, Chapel Hill, N.C.
Hon. Marion B. Folsom, chairman, National Commission on Community Health Services (former Secretary of Health, Education, and Welfare).
Dr. John H. Hanlon, commissioner of health, Detroit, Mich.
Dr. George James, dean, Mount Sinai Medical School, and chairman, Task Force on Community Assessment, Planning, and Action of the National Commission on Community Health Services.
Dr. Stanley P. Mayers, director of public health, Arlington, Va.
Dr. Mack I. Shanholtz, commissioner, Department of Health, Commonwealth of Virginia.
Dr. David J. Vail, director of medical services, Minnesota Department of Public Welfare.
Dr. John H. Venable, director, Georgia Department of Public Health.
Dr. Myron Wegman, dean, School of Public Health, University of Michigan.
Dr. Charles L. Wilbar, Jr., secretary of health, Commonwealth of Pennsylvania.

On April 21–22, 1966, the subcommittee conducted a roundtable discussion on the status of the Federal-State-local health partnership. To moderate this discussion, the subcommittee was fortunate to have the distinguished public health expert, Dr. Herman E. Hilleboe, formerly New York State health officer, and presently professor of administrative medicine and public health at Columbia University. The participants at this roundtable included 15 distinguished experts in the field of public health, drawn from a wide geographic area, and representing various levels of government, as follows:

Dr. Lester Breslow, director, California State Department of Public Health.
Dr. James L. Dennis, director and dean, University of Oklahoma Medical Center.
Dr. Alfred L. Frechette, commissioner, Massachusetts Department of Public Health.
Dr. Robert Kimmich, director, Michigan Department of Mental Health.
Dr. Berwyn Mattison, executive director, American Public Health Association.
Dr. William J. Peeples, commissioner, Maryland State Health Department.

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Dr. John R. Philp, director of health, Kansas City, Mo.
Dr. Julius Richmond, program director, Project Headstart, Office of Economic Opportunity.
Dr. Wilson T. Sowder, State health officer, Florida State Board of Health.
Dr. William Stewart, Surgeon General of the United States.
Miss Mary E. Switzer, Commissioner, Vocational Rehabilitation Administration.
Dr. G. D. Carlyle Thompson, director of public health, State of Utah.
Dr. Ellen Winston, U.S. Commissioner of Welfare.
Dr. Stanley F. Yolles, Director, National Institute of Mental Health.

During the roundtable discussion, the subcommittee also heard testimony from:

Hon. Wilbur J. Cohen, Under Secretary of Health, Education, and Welfare.
Dr. Philip R. Lee, Assistant Secretary, Health and Scientific Affairs, Department of Health, Education, and Welfare.
Dr. Arthur Lesser, Children's Bureau, Welfare Administration, Department of Health, Education, and Welfare.
Dr. Carl Mulder, Assistant Chief, Division of Medical Services, Bureau of Family Services, Department of Health, Education, and Welfare.
Alanson W. Willcox, Esq., General Counsel, Department of Health, Education, and Welfare.

This roundtable discussion was organized to explore, in depth, three major criticisms of the operations and organization of the Department of HEW which tend to impair the effectiveness of the Federal-State-local health relationship. The topics of discussion were as follows:

A. Fragmentation of Federal health activity, and its effect on State and local health programs.

B. The alleged tendency of Federal authorities to bypass State health authorities when sponsoring health projects and activities within the States.

C. The desirability of allowing the States greater flexibility in spending Federal grant money.

On May 27, 1966, the subcommittee heard testimony from the Honorable John W. Gardner, Secretary of Health, Education, and Welfare; accompanied by Dr. Philip R. Lee, Assistant Secretary for Health and Scientific Affairs; Mr. Donald Simpson, Assistant Secretary for Administration; and Surgeon General William H. Stewart, on the proposed reorganization of the Public Health Service pursuant to the authority granted to the Secretary of HEW by Reorganization Plan No. 3 of 1966 (see appendix B).

Dr. James L. Goddard, Commissioner of Food and Drugs; accompanied by Dr. Philip R. Lee, testified before the subcommittee on June 20, 1966, in regard to reorganization of the Food and Drug Administration (see appendix H).

The subcommittee has also considered the problems arising from shortages in the Nation's available supply of medical and paramedical personnel, and the Department's activities relative to this problem (see part B, this report). A review of the activities of the National Institutes of Health was conducted with particular emphasis on the

adequacy of NIH mechanisms for long-range planning and the efficiency and effectiveness of NIH program administration. (See Part C).

The subcommittee's review of the activities of the Food and Drug Administration will be found in Part D. Part E contains a review by the subcommittee of current problems with respect to biomedical communications activities.

PART A—HEALTH SERVICES—THE FEDERAL-STATE-LOCAL PARTNERSHIP

Part A—Health Services—The Federal-State-Local Partnership

I. INTRODUCTION

This portion of the subcommittee report centers on the provision of health services. It is important to recognize the specialized problems existing in this area, as contrasted to, for example, the support of biomedical research, or the improvement of biomedical communications. While it is probably true that the general field of health is so interwoven that no single health activity may be said to stand apart from others, there are, nevertheless, basic problems in the delivery of health services which merit individual attention. These problems are long standing but, in the opinion of the subcommittee, have become increasingly acute in recent years.

The vast Federal effort in support of basic biomedical research has already been documented and discussed in many reports, originating from within and without the Congress. The wholesale generation of scientific discovery and information, however, cannot of itself directly contribute to the individual's health and well-being. It is only when the fruits of discovery are delivered to the ultimate consumer that the cycle is complete. This thought was expressed frankly by Dr. John J. Hanlon, health commissioner of the city of Detroit and public health director of Wayne County, Mich., in his testimony before the subcommittee:

> The manufacturer in the building of a production plant accomplishes nothing. The actual building of the automobiles accomplishes nothing. The only thing that counts in the final analysis is the actual sale and use of an automobile by the consumer. We are selling a product—health—and everything that is done on every level of government, be it in the National Capital, the State capital, a city hall, or a county building, is worthless except to the extent that a worthwhile product is delivered to the person who needs the help.[1]

In the view of the subcommittee, it is this activity—the delivery of health services to the person needing the help—which has become critical in the Nation's pursuit of better health for all of its citizens. The subcommittee's study has determined that the application of biomedical research advances into concrete health services and the subsequent delivery of these services to the ultimate consumer are the weak links in the national health effort. Recently, a distinguished panel investigating the National Institutes of Health, a component of the U.S. Public Health Service, expressed a similar thought:

> "Planning" is perhaps the rubric under which the Panel should mention its perplexity over the apparent absence of any obvious large activity or intense concern to apply the results of biomedical research to improve human health and longevity.
>
> In other technical fields there are easily recognizable channels for the movement of ideas, inventions, and discoveries from the laboratory to the market-place, and at every point along such a channel there is an easily recognizable economic incentive for someone to keep the flow going. It is not clear to the Panel just what analogous pattern of channels and incentives exists in the health field. * * *

[1] Hearings before HEW Investigation Subcommittee, April-June 1966, p. 72.

We would expect that NIH, whether it has much or little responsibility for the ultimate application of useful research results, would be actively interested in the pattern of mechanisms which make these results available to the practitioner and his patient.[2]

The "pattern of mechanisms" which bring home the fruits of biomedical research to the ultimate consumer, constitute the final step in the process of improving the Nation's health. In taking this final step, the individual efforts of the scientific investigator must give way to the efforts of the Federal, State, and local agencies whose duty it is to provide and support health services. This step, calling for a well-coordinated effort involving all levels of government—none of which can do the job alone—is the one most in need of review and improvement.

In the opinion of the subcommittee, the present status of the Federal-State-local health partnership must be greatly improved if the American people are to receive the full benefits from the biomedical research in which their tax dollars have been invested. The subcommittee has noted important areas where the organization and the policies of the Federal Government, specifically the Department of HEW, have diminished the effectiveness of the Federal-State-local health partnership. While the increasing initiative of the Department in seeking ways in which to improve the effectiveness of this partnership is encouraging, it should not give rise to complacency.

II. The Federal Government's Widespread Health Programs

Although the U.S. Public Health Service is generally thought to be the main center of health activity within the Federal Government, major health programs are also found in each of the other seven constituent agencies of the Department of Health, Education, and Welfare—the Administration on Aging, Office of Education, Food and Drug Administration, Social Security Administration, St. Elizabeth's Hospital, Vocational Rehabilitation Administration, and the Welfare Administration. Furthermore, even though one of the purposes in establishing the Department of Health, Education, and Welfare was to improve the administration of the health activities of the Government, there are still many health activities carried on by the Federal Government which are administered outside of the Department and completely beyond its control.

Before focusing on the Department of Health, Education, and Welfare, therefore, it would be well to consider the magnitude of the total Federal effort in the field of health. This will help to place the health activities of the Department in perspective. The information which follows, while presented in condensed form, will indicate the dimensions of the growing national commitment to health for all citizens. Cash payments by the Federal Government to the public in the broad category of health will rise to an estimated total of $10.3 billion in 1967. This total comprises $7.8 billion in expenditures from administrative budget accounts, and $3.3 billion from trust funds, less interfund transfers of $0.8 billion. Table I indicates the various categories under which these expenditures will be made.

[2] "Biomedical Science and Its Administration—A Study of the National Institutes of Health." Report to the President, February 1965. Report of the Administration Panel, pp. 111–112.

TABLE I.—*Federal expenditures for medical and health-related activities by category*

[In millions of dollars]

Category	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	2,022.0	2,209.0	2,397.9
Federal grants and payments for hospital and health care in non-Federal facilities	913.8	1,374.9	4,623.1
Medical research, total	1,040.1	1,320.6	1,448.3
(*a*) Conduct of research	(965.5)	(1,214.2)	(1,325.1)
(*b*) Research facilities	(74.6)	(106.4)	(123.2)
Training, including training for research	316.9	448.9	546.1
Prevention and community services	417.6	493.7	634.5
Construction of hospitals and health facilities	449.9	468.4	672.3
Total expenditures from administrative budget and trust accounts	5,160.3	6,316.4	10,322.2

Source: U.S. Bureau of the Budget.

Among the major Federal agencies, other than HEW, which administer Federal health programs are the following:

Department of Agriculture.
Atomic Energy Commission.
Civil Service Commission.
Department of Defense.
Department of Housing and Urban Development.
Department of the Interior.
Department of Justice.
Department of Labor.
National Aeronautics and Space Administration.
Office of Economic Opportunity.
Small Business Administration.
Department of State.
Veterans Administration.

Appendix A of this report contains brief summary statements of the major health activities of the above agencies. Table II lists Federal expenditures for medical and health-related programs by individual agency:

TABLE II.—*Federal expenditures for medical and health-related programs by agency*

[In millions of dollars]

Agency	1965 actual	1966 estimate	1967 estimate
ADMINISTRATIVE BUDGET			
Department of Health, Education, and Welfare:			
Public Health Service:			
National Institutes of Health	779.8	1,000.0	1,150.0
Other	603.7	737.1	880.0
Water Pollution Control Administration	100.9	121.0	181.5
Welfare Administration	628.3	920.8	929.2
Social Security Administration		37.0	844.0
Other	97.4	128.9	168.9
Total, Department of Health, Education, and Welfare	2,210.1	2,944.8	4,153.6
Veterans Administration	1,265.7	1,343.0	1,386.5
Department of Defense:			
Army	463.3	563.7	748.7
Navy	200.6	255.1	287.0
Air Force	400.7	414.3	420.2
Other	1.7	2.1	2.5
Total, Department of Defense	1,066.3	1,235.2	1,458.4
Agency for International Development	50.6	60.0	92.0
Atomic Energy Commission	90.1	95.4	102.6
Department of Agriculture	114.2	122.5	128.2
National Aeronautics and Space Administration	50.6	79.1	75.6
Department of Housing and Urban Development	39.8	27.2	87.1
National Science Foundation	25.9	35.1	35.9
Civil Service Commission	27.0	29.2	31.7
Office of Economic Opportunity	5.6	39.0	74.9
Department of State	19.5	21.9	23.8
Department of Labor	17.8	17.8	20.3
Department of Justice	7.8	7.7	8.0
Peace Corps	5.9	7.2	7.5
Panama Canal	7.3	7.8	7.8
Small Business Administration	8.3	8.5	10.3
Department of the Interior	4.4	4.9	4.9
General Services Administration	1.9	.7	
U.S. Information Agency	.4	.4	.4
Federal Aviation Agency	1.7	1.7	1.7
Military assistance program	15.0	15.0	20.0
Transitional grants to Alaska	.9	.3	
Contributions by Federal agencies to Federal employees' health benefits funds not included above	126.7	127.6	129.1
Total net budget expenditures for health	5,163.5	6,232.0	7,860.3
Interfund transactions		−37.0	−844.0
TRUST FUNDS			
Department of Health, Education, and Welfare: Social Security Administration		105.0	3,305.0
Civil Service Commission, net	−10.0	8.6	−7.9
U.S. Soldiers' Home	6.9	7.4	8.5
Railroad Retirement Board		.4	.3
Total trust fund expenditures for health	−3.2	121.4	3,305.9
Total budget and trust fund expenditures for health	5,160.3	6,316.4	10,322.2

Source: U.S. Bureau of the Budget.

While the mere recitation of budget figures can serve only as a rough indication of the health activities of the Federal agencies, it does serve to underline the fact that a large percentage of Federal health programs operate outside of HEW—the Department which has primary responsibility for the nation's health.

In view of the very large amounts of tax dollars devoted to health activity by the Federal Government, inefficiency of administration is a critical matter. This fact also underlines the importance to the Nation of a viable and effective Federal-State-local health partnership. As stated in the report of one of our sister committees:

> The value of a healthy population for our national security and well-being is self-evident. Research might be regarded as one of the two main supports on which the health of the Nation rests. The other is the application of the fruits of research, and medical knowledge and skills in general, in the form of services to the people.[3]

Health services, the second main support of the Nation's health, is the subject under consideration. Despite the increasing complexities of technology and science, the frontier of scientific discovery, the "growing edge" of knowledge is still primarily the domain of the individual investigator. The application of scientific discoveries to alleviate suffering and to promote well-being, however, requires complex organizational and administrative arrangements.

These arrangements must provide for an orderly sharing of responsibility, and should allow for the appropriate exercise of initiative by the various organizational units which are to provide the services. Through disposition of Federal funds, the Federal Government—the Department of HEW in particular—exercises great influence in determining the characteristics of the organization and delivery of health services in this country. In designing its own policies and organizational mechanisms, the Federal Government must always seek to strike a balance between a proper accountability for public funds and a proper scope for State and local initiative and innovation. Complexity of organization and strictness of regulations cannot, of themselves, bring about efficiency in the administration of health services, and may actually impair administration. From the subcommittee study, it appears that the present arrangements at the Federal level for the administration of health services are overly rigid and complex; the administration of medical care activities at the State and local levels may be impaired as a result. The subcommittee is of the opinion that a simplification of the Federal organizational structure and a relaxation of the stringency of Federal regulations would result in an improvement in the workings of the Federal-State-local health partnership.

Fragmentation of health services

If one word could be used to describe the difficulties presently besetting this partnership, it would be "fragmentation". Fragmented authority and responsibility in health matters is a problem within the Federal Government as a whole, and within the Department of HEW individually. While the Nation has been committed to a war against disease and substandard health, the Federal forces arrayed in the struggle are scattered, and their activities are not effectively coordinated.

This organizational fragmentation within the Department of HEW arises from the fact that several agencies frequently may administer programs providing essentially the same type of services to the same type of beneficiaries. This has had its effect on

[3] "Health Research and Training—The Administration of Grants and Awards by the National Institutes of Health—Second Report by the Committee on Government Operations," 87th Cong., 1st sess., H. Rept. No. 321 (1961), p. 1.

State governments as well, since there is a natural tendency on their part, encouraged by Federal regulations and policies, to reflect the Federal organization to some degree. While no State has an agency equivalent to the Department of HEW, the attempt to establish direct channels of communication with Federal agencies administering the diverse grant programs which presently characterize the Federal health activity has resulted in a fragmentation of health services administration at the State level.

A State or local health officer seeking to obtain Federal support for a planned activity may find it necessary to deal with two, or more, semiautonomous agencies within the Department of HEW. The representatives of such agencies, recognizing no duty to subordinate their own criteria and regulations to those of other HEW agencies, may at times attach conditions to the receipt of Federal funds which they administer that are inconsistent, or even irreconcilable, with those of their fellow agencies. Such situations can and do arise when different agencies within HEW have jurisdiction for supporting and administering similar programs involving the same segments of the population.

As a result of the fragmentation of Federal health programs in different Federal agencies, State and local health authorities are forced to go shopping in the "Federal market" for various bits and pieces of an overall health program.[4] The present structure was characterized by one witness as a "special professional interests arcade".[5] The result of this organizational and program fragmentation is to raise a barrier against sound and comprehensive planning for health services at the State and local levels; funds are often available for unneeded programs and unavailable for other programs which may be more urgent in a given State or locality.

The burden imposed by the present fragmentation seems to be especially severe in the case of the smaller States. The Honorable John H. Chafee, Governor of Rhode Island, told the subcommittee:

> In reviewing Federal-State-relations, it is my belief that present arrangements do not permit the full exploitation of current knowledge, nor the delivery to the people of my State the latest developments in public health. The factors which seem to interfere with this objective are: (1) the dispersion of health services; and, (2) restrictive Federal financing.[6]

The Governor conceded that the fragmentation of health services throughout various departments or divisions exists at the State level as well as the Federal level. Nevertheless, he as well as the majority of health experts consulted by the subcommittee, felt that the fragmentation of health services at the State level is the result of the fragmentation presently existing at the Federal level:

> As far as possible certainly the States should put their own houses in order, but in so doing there is the risk of tearing up well-developed relationships with the Federal counterpart and in some instances the existing arrangement is actually required or has been required, by Federal law. For example, our State's division of vocational rehabilitation, which is ever increasing in size, because of existing Federal legislation, is located within our department of education. This department has no medical orientation and does not seek any, while, of course, vocational rehabilitation has primarily medical responsibilities and should be in our health department. Interdepartmental cooperation in our State can reduce the possible confusion in this area, but an outright transferral would be superior.[7]

[4] Hearings, pp. 72–73.
[5] Id., p. 62.
[6] Id., pp. 3–4.
[7] Id., p. 4.

Even for regular medical problems, there are a variety of Federal programs which must somehow be coordinated and brought together at the State and local level. The following illustrative example was presented to the subcommittee:

Let us take the case of a 15-year old boy on aid to dependent children who has a hearing problem that can be corrected. My natural response, as I am sure yours is too, would be, "correct his hearing." However, confusion arises when one considers whether he should be referred to the public assistance medical care program administered by the Department of Social Welfare, the Division of Vocational Rehabilitation administered by the Department of Education, or to the crippled children's program administered by the Department of Health. Under such conditions there is the temptation—and I might say this is a very real one—to refer such a patient not to the program which is best organized to meet his particular need, but to the program in which the State obtains the best financial advantage. The Federal Government will pay 50 percent of the cost when the care is provided by the Crippled Children's Division; it will pay 56 percent under title XIX since he is on aid to dependent children and, if he is cared for by vocational rehabilitation, the Federal Government will soon pay 75 percent of the bill. Each of these programs have some variations in standards for eligibility but nonetheless the differences in Federal reimbursement seem extremely puzzling.[8]

There is a definite tendency for the specialized and fragmented "donor agencies" at the Federal level to desire counterparts in the State organizations. The limited nature of specialists' interests may often be expressed in detailed restrictions which vary from special fund to fund, and from agency to agency. This can, and does, result in such mutually exclusive demands as to render the giving of service locally a near impossibility:

In our own immediate experience the Children's Bureau set up such restrictions on three separate funds. What should have been a beautifully integrated service as well as a study and demonstration of some new ways to render maternal and infant care, well-child care, and general childhood medical care in a continuous one-source-of-care pattern has been left in a shambles. One fund will only tolerate the use of medical specialists, but our area of need has no specialists; one will only tolerate clinics as a source of care; and one will only allow us to include patients from certain poverty areas but not for poor persons in the larger general area that would need services from the other two funds.

In other words, even in one part of one county there can be no continuity of care provided for between the three funds for the same people. Nor can the same families receive what they need from pregnancy through delivery (one fund), to well-child care (another fund), and inclusive of sick care (a third fund).[9]

The confusion, wasted effort, and frustration for the local public health authorities trying to provide health services to their citizens does not stop here, however:

At the same moment OEO, through Headstart, is providing short-term services for preschoolers of the same poverty areas and migrant health funds are coming in to the same area for seasonal residents. The mothers in these families can get family planning under the Children's Bureau funds but not through OEO funds. The details, the public confusion, the local policymakers' attempt to participate, and the shift from specification to specification according to fund result in unbelievable agency frustration. Obviously, darn little service occurs.[10]

The ultimate loser under the present fragmented system of delivering health services is the individual who needs help. Dr Lester Breslow, director of the California State Department of Public Health presented the following case to the subcommittee:

I would like to discuss fragmentation from the point of view of how these several programs which the Congress has initiated really impinge on a mother.

[8] Id., p. 4.
[9] Id., p. 110.
[10] Ibid.

Let us assume a mother who is receiving aid to families with dependent children. The most likely medical event in her life is to have another pregnancy and another child. Let us follow the process through, assuming that the mother is intelligent and highly motivated.

She would start off by seeking care for her pregnancy, prenatal care from a health department clinic supported perhaps by maternal and child health funds. However, when the time came for delivery she would be sent to a public hospital supported by local funds; there she would encounter a new group of doctors, receptionist's forms, and papers.

In the hospital she would be examined by a physician and her infant would be examined by a physician. Neither of them would see her agian.

She would take the child home. Being an intelligent, highly motivated mother, she would take her child to a health clinic. There she would get well-baby care and perhaps immunization. However, the baby might get sick. She would take the sick baby to the clinic. They would tell her that they only care for well babies. Because the child is now sick, she must take the baby to a welfare medical care program, perhaps the doctor over the drugstore on her corner. She would take the child there, and he would provide care for a few days. The baby might then become quite ill and have to go to the hospital. She would take the baby to the welfare program doctor thinking he would admit the baby to the hospital. But that program does not provide for hospital care. She would take the baby back to the public hospital.

Even this might not be the end of the story, because the child might be eligible for crippled children's services and have to go to a different hospital.

I submit that if a man from Mars looked at this situation he would think that the whole scheme had been designed to obstruct care, not to provide it; he might be right, as a matter of act. We should not talk about the motivation or intelligence of these people so glibly. If any of us, or our families, had to go through such stress and turmoil to get ordinary care, I think we would have a great deal of difficulty and might become discouraged.[11]

The fragmentation referred to above is an organizational fragmentation impairing efficient administration.

Another type of fragmentation may be termed "program fragmentation." This involves piecemeal programs supporting only one distinct type of health service activity, rather than a broad range of health functions. Examples would be specific project grants for venereal disease control, tuberculosis control, and heart disease control. The State or local administrator receiving such fragmented funds must scrupulously avoid "contaminating" one fund by allowing any of it to support activities (including personnel salaries) other than those within the specific purpose for which it is awarded. This has been carried to the extreme of necessitating that public health nurses at the State and local levels be employed, on a specialized basis, for the different categorical programs. As another example, if a State health department wishes to take advantage of the Federal assistance available for water pollution control activities, it may be necessary to seek assistance simultaneously from five different Federal departments—Interior, HEW, Housing and Urban Development, Commerce, and Agriculture. Each of these entities has its own regulations which must somehow be reconciled in order to finance the complete program; a specific project can be financed by one or all of these departments.[12] The same situation obtains in the field of mental retardation, where assistance may be sought from both the Maternal and Child Health Division and the Crippled Children's Division of the Children's Bureau (a subdivision of HEW, Welfare Administration), and also from the Public Health Service Division of Chronic Diseases. If construction funds are desired, they must be sought elsewhere in the Federal tangle of health agencies.[13]

[11] Id., pp. 231–232.
[12] Id., p. 4.
[13] Ibid.

Finally, it should be noted that the two types of fragmentation just described are not mutually exclusive; they can coexist, and do in many instances. Certainly, one of the most serious drawbacks of the present fragmented structures of the health-related programs and organizational subunits within HEW is that they impair the orderly working of the Federal-State-local health partnership.

This fragmentation in health authority and responsibility, both at the Federal and the State level, was deplored by virtually every authority in the field of public health contacted by the subcommittee; they emphasized the unities which exist in the health needs of people, and emphasized the need for a unified and coordinated approach by all government levels in the field of health services.

The struggle against disease and substandard health must, at some basic level, conform to the same sound organizational principles which apply to organized struggles against other forms of social and physical ills. Society could not tolerate, for example, the existence of rival police departments working independently and without coordination while seeking to safeguard the same geographic areas and to solve the same crimes. Similarly, the picturesque, and inefficient, rival fire companies which were common earlier in this century have given way to more rational arrangements. While analogies of this type cannot be pressed too far, it does seem to the subcommittee that, as a matter of sound administration of government services, no two administrative units, be they for fire, crime, or disease prevention, should be employed in rendering the same services to the same recipients, or "clients." While we have succeeded in setting up administrative mechanisms which make the most efficient use of our firemen and policemen, the same, unfortunately, cannot presently be said of the arrangements which exist for the utilization of our scarce pool of medical and paramedical personnel.

III. The Department of Health, Education, and Welfare

A. HISTORICAL DEVELOPMENT

A brief summary of the history of HEW will serve to place some of the subcommittee's findings and recommendations in more specific context. The Department had its origin in the attempt to group in a single agency all Government agencies whose major purpose was the promotion of social and economic security, educational opportunity, and health. In his message to Congress accompanying Reorganization Plan No. 1 of 1939, President Roosevelt stated:

> I find it necessary and desirable to group in a Federal Security Agency those agencies of the Government, the major purposes of which are to promote social and economic security, educational opportunity, and the health of the citizens of the Nation.[14]

The agencies grouped in the original Federal Security Agency were the Social Security Board, then an independent establishment; the U.S. Employment Service, then in the Department of Labor; the Office of Education, then in the Department of the Interior; the Public Health Service, then in the Treasury Department; the National Youth Administration, then part of the Works Progress Administration; and the Civilian Conservation Corps, an independent agency. The

[14] Congressional Record, vol. 84, pt. V, p. 4710, 76th Congress, 1st sess.

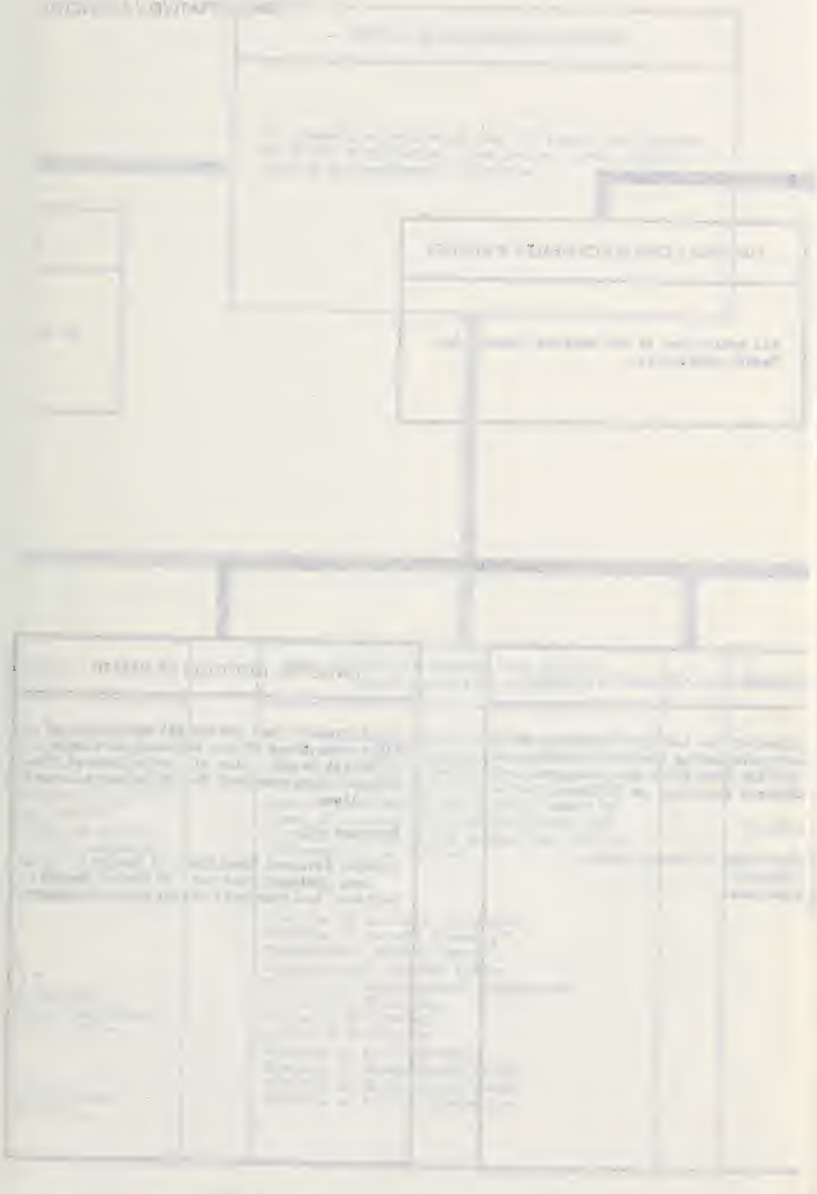
Federal Security Agency later incorporated the Food and Drug Administration (1940) from the Department of Agriculture and the Children's Bureau (1946) from the Department of Labor.

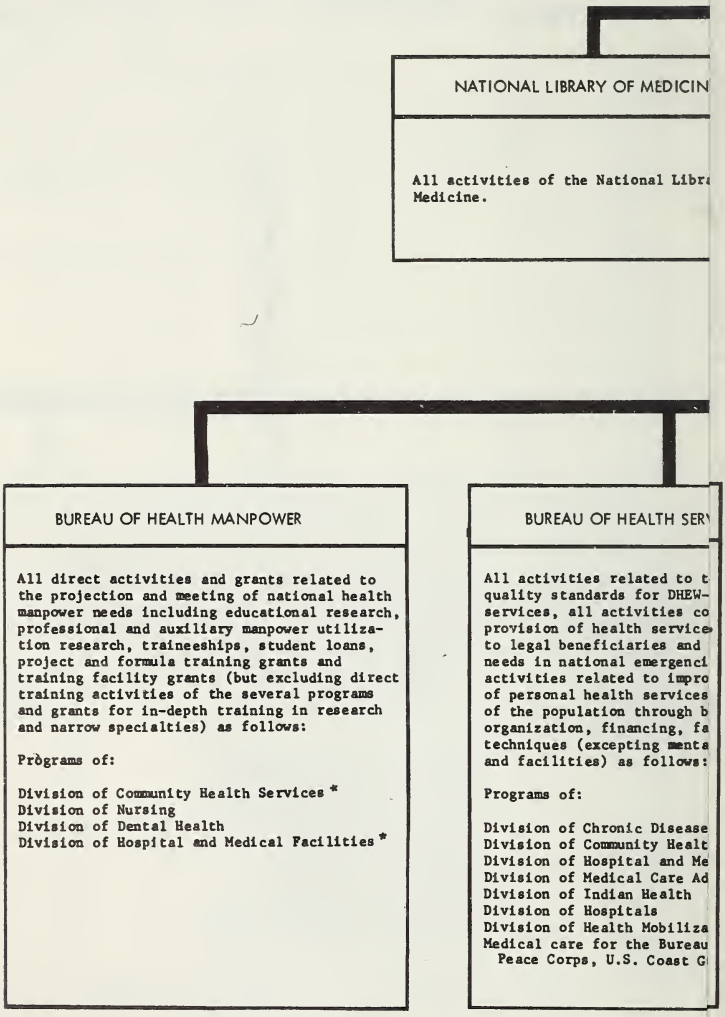
The present Department of Health, Education, and Welfare was created by Reorganization Plan No. 1 of 1953. This plan abolished the Federal Security Agency and transferred all the functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare and all components of the Agency to the Department. The primary purpose of this plan was to improve the administration of the vital health, education, and social security functions then being carried on in the FSA by giving them departmental rank. The plan did not materially alter the grouping of functions within the Federal Security Agency.

The Department of HEW, therefore, is not an administrative unity specifically designed to accomplish its mission. Rather, it represents an attempt to impose coordination and unified control over those agencies of the Government concerned with health, education, and social security. HEW is therefore, constituted by units of differing organization, expertise, and interests. A good number of these have their own strong traditions, and histories which predate the present Department. The Public Health Service, for example, had its origin in an act of Congress approved in 1798. It resided in the Department of the Treasury for nearly 150 years until it was transferred in 1939 to the Federal Security Agency. Likewise, the Children's Bureau was founded in 1912, and originally located in the then Department of Commerce and Labor. It was assigned to Labor when that Department was split off in 1913 and was relocated in the Federal Security Agency in 1946.

Other examples might be cited; however, these serve to illustrate the variety and distinctiveness of the various agencies now located within the Department. This has led some to characterize HEW as merely a "holding company." Although this characterization appears to be somewhat less valid now than in the past, the subcommittee feels that there is a continuing need for strong direction and leadership if the Department is to avoid functioning as a mere confederation of agencies rather than an effective instrument for sustained Federal effort in the field of health.

Many of the agencies which constitute HEW were originally established in response to social and governmental changes which could not have been anticipated and planned for on a step-by-step basis. Many were created to carry out what were, at the time of their inception, new and specialized functions. The Federal Government has now moved into a broader and more comprehensive activity in the field of health. While there is still need for pioneering and innovation in health services, the Department of HEW must be prepared to administer a sustained and coordinated effort in the health field. There must be a continuing insistence by its leadership that the various units constituting HEW, whatever their origins and traditions, subordinate their own autonomy to the overall health effort of the Department.





* Those programs in the Division which relate primarily to this Bureau.

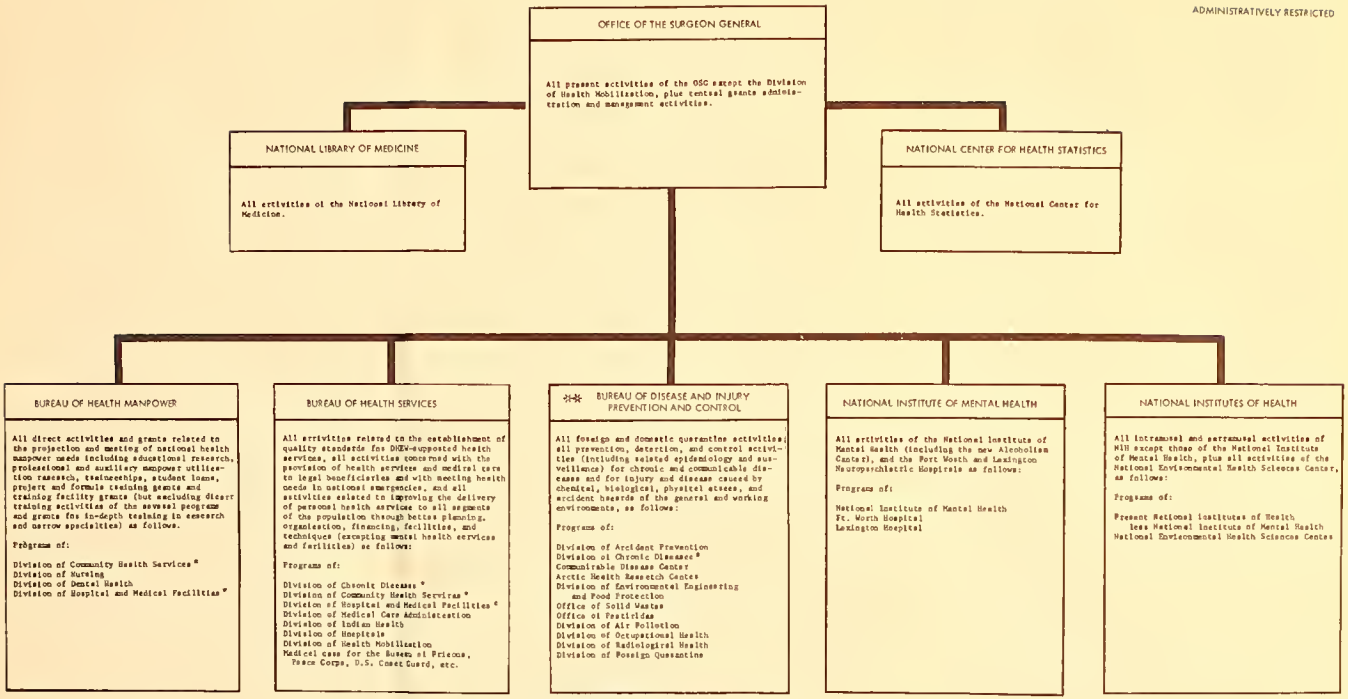
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FIGURE 3

PROPOSED ORGANIZATION OF THE PUBLIC HEALTH SERVICE

ADMINISTRATIVELY RESTRICTED

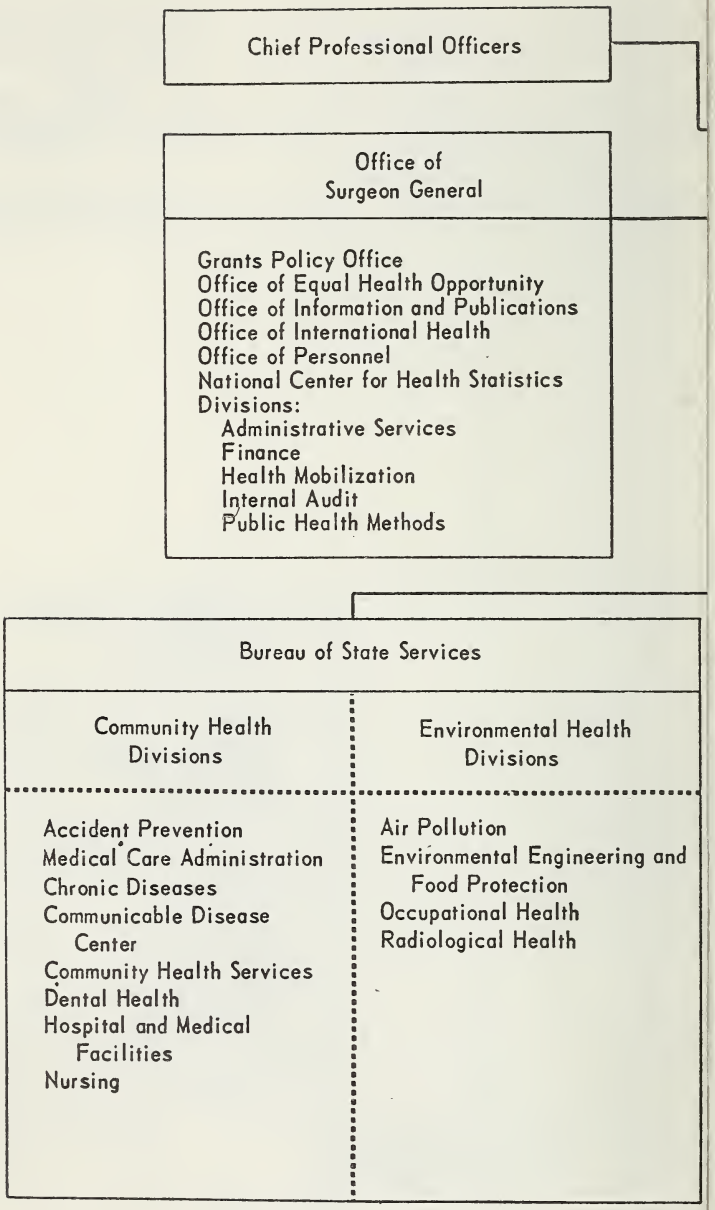


* Those programs in the Division which relate primarily to this Bureau.

**Subsequently changed to: Bureau of Disease Prevention and Environmental Control

4-18-66

PRESENT

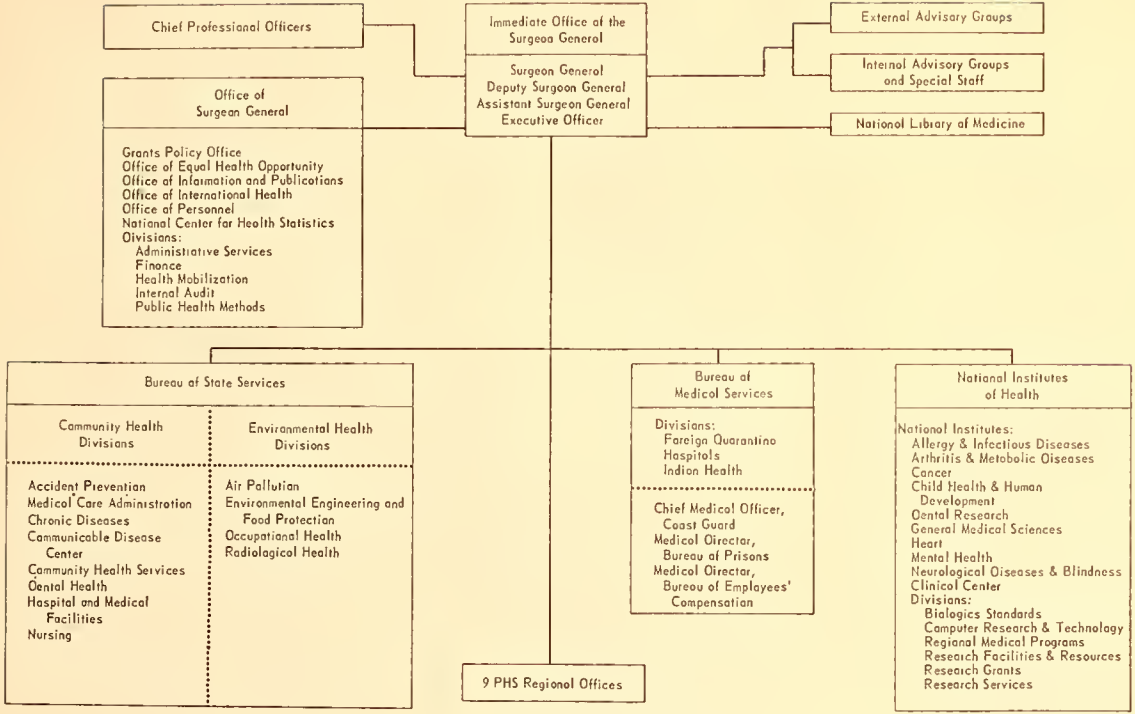


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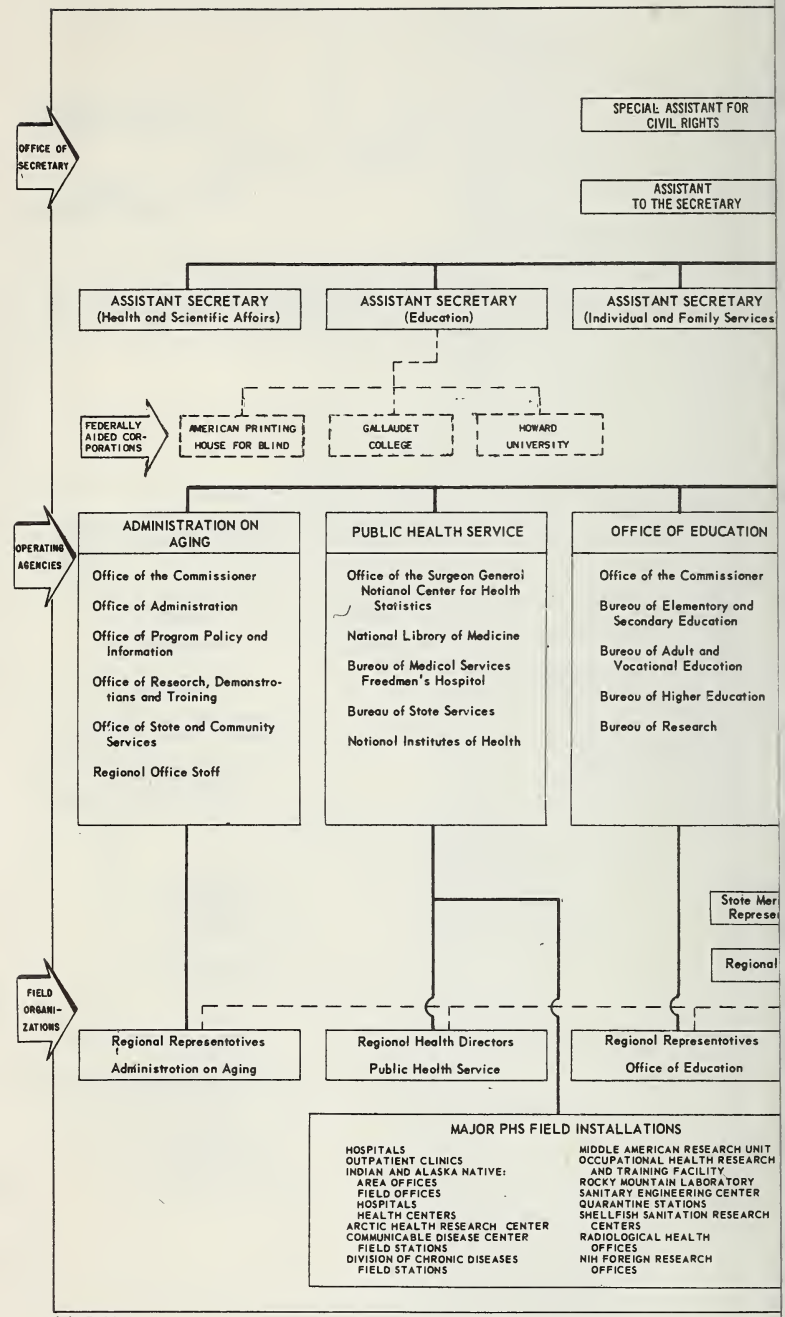


FIGURE 2

PRESENT ORGANIZATION OF THE PUBLIC HEALTH SERVICE







July 7, 1966

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B. PRESENT HEALTH SERVICE ACTIVITIES OF HEW

The present organizational structure of the Department of Health, Education, and Welfare is illustrated by the following organizational chart (figure 1):

The principal agency within HEW responsible for the provision of health care, and for financial assistance to State and local governments for health services, is the U.S. Public Health Service. The organizational structure of this unit is to be modified under the terms of the President's Reorganization Plan No. 3 of 1966, which became effective on June 25, 1966 (see appendix B). The present organizational structure of the Service is set forth in figure 2, and the proposed reorganization of the Service, pursuant to Reorganization Plan No. 3, is illustrated by figure 3.

A detailed description of the health functions and activities of the various agencies within the Department of HEW, including the Public Health Service, will be found in the subcommittee print entitled "Background Material Concerning the Mission and Organization of the Health Activities of the Department." This two-volume document was prepared for this subcommittee and printed in March of 1966. While the pending reorganization under the authority contained in Reorganization Plan No. 3 of 1966 will modify the structure of the Public Health Service, the subunits comprising the PHS will retain, for the most part, the responsibilities and activities described in the subcommittee print.

In considering the health service activities of the Department of HEW, it is important to bear in mind that the term "health services" generally is used with different meaning in referring to different categories of Americans. There are groups of citizens to whom the Government is committed for full medical care (e.g., military personnel and their dependents, eligible veterans of the U.S. Armed Forces, Federal prisoners, etc.). There are other health activities performed by HEW which have more general application to all citizens. The primary concern of this report is with the latter category.

It is difficult to arrive at a precise definition of the term "health services" since the term can include a great variety of activities. The term includes those programs and activities of the Department which support, either directly or indirectly, the actual delivery of health care to people. Examples are the specific health services project grants, such as the tuberculosis control and venereal disease control grants. Formula grants to the States for health services, such as the general health grants and the home health services grants are also included.

The importance of effective Federal-State-local dialogue and joint planning is much greater in the area of health services than it is in the area of pure research. The ability of a state or metropolitan health officer to administer a sound and well-balanced program does not require that he be consulted or informed about every basic biomedical research project being carried out in the universities in his State or city. This type of Federal support can be, and perhaps should be, removed from the sector of Federal-State-local joint participation. The need for close Federal-State-local coordination is critical, however, in the field of grants which support delivery of health services. Therefore, the construction of health facilities, conduct of screening

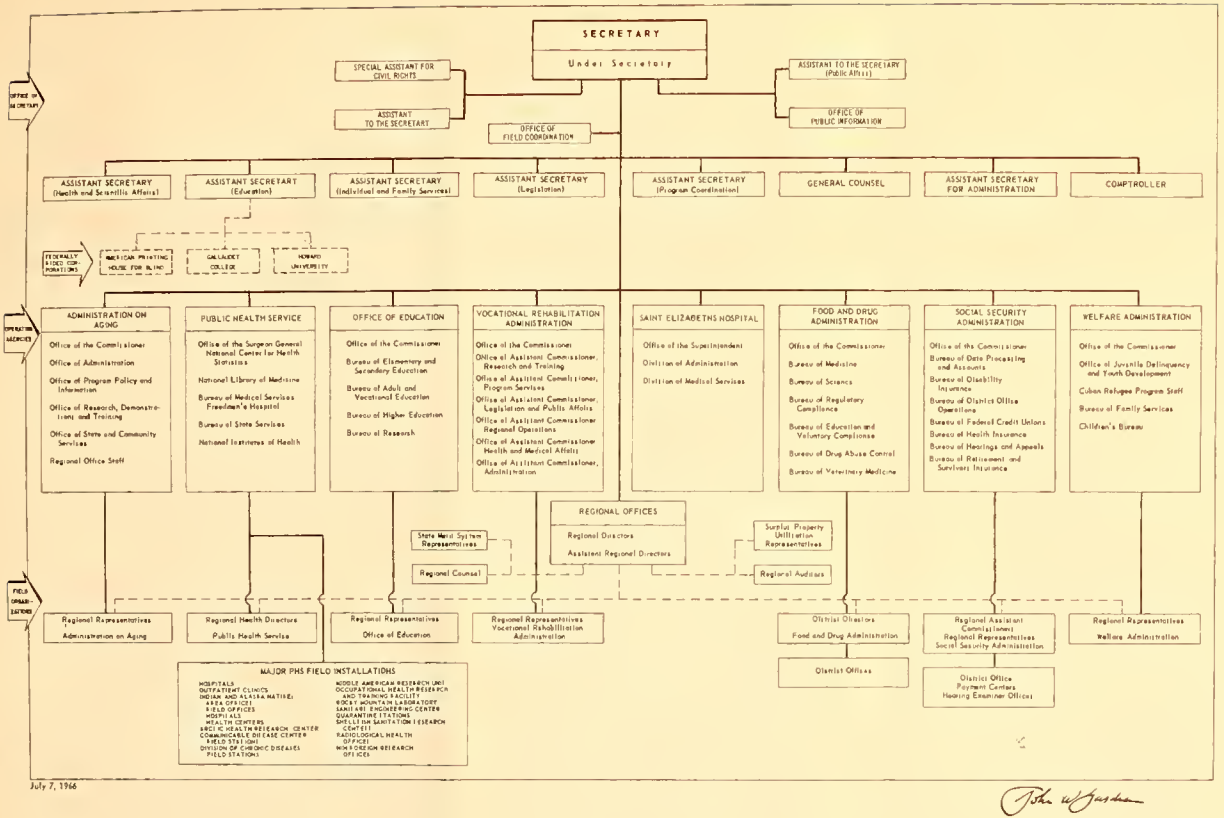

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
SECRETARY
Under Secretary
SPECIAL ASSISTANT FOR CIVIL RIGHTS
ASSISTANT TO THE SECRETARY
OFFICE OF FIELD COORDINATION
ASSISTANT TO THE SECRETARY (Public Affairs)
OFFICE OF PUBLIC INFORMATION
OFFICE OF THE SECRETARY
ASSISTANT SECRETARY (Health and Scientific Affairs)
ASSISTANT SECRETARY (Education)
ASSISTANT SECRETARY (Individual and Family Services)
ASSISTANT SECRETARY (Legislation)
ASSISTANT SECRETARY (Program Coordination)
GENERAL COUNSEL
ASSISTANT SECRETARY FOR ADMINISTRATION
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ADMINISTRATION ON AGING
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Office of State and Community Services
Regional Office Staff
PUBLIC HEALTH SERVICE
Office of the Surgeon General
National Center for Health Statistics
National Library of Medicine
Bureau of Medical Services
Freedmen's Hospital
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Bureau of Research
VOCATIONAL REHABILITATION ADMINISTRATION
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Office of Assistant Commissioner Health and Medical Affairs
Office of Assistant Commissioner, Administration
SAINT ELIZABETHS HOSPITAL
Office of the Superintendent
Division of Administration
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FOOD AND DRUG ADMINISTRATION
Office of the Commissioner
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Bureau of Drug Abuse Control
Bureau of Veterinary Medicine
SOCIAL SECURITY ADMINISTRATION
Office of the Commissioner
Bureau of Data Processing and Accounts
Bureau of Disability Insurance
Bureau of District Office Operations
Bureau of Federal Credit Unions
Bureau of Health Insurance
Bureau of Hearings and Appeals
Bureau of Retirement and Survivors Insurance
WELFARE ADMINISTRATION
Office of the Commissioner
Office of Juvenile Delinquency and Youth Development
Cuban Refugee Program Staff
Bureau of Family Services
Children's Bureau
REGIONAL OFFICES
Regional Directors
Assistant Regional Directors
State Merit System Representatives
Regional Counsel
Surplus Property Utilization Representatives
Regional Auditors
FIELD ORGANIZATIONS
Regional Representatives
Administration on Aging
Regional Health Directors
Public Health Service
Regional Representatives
Office of Education
Regional Representatives
Vocational Rehabilitation Administration
District Directors
Food and Drug Administration
District Offices
Regional Assistant Commissioners
Regional Representatives
Social Security Administration
District Office
Payment Centers
Hearing Examiner Offices
Regional Representatives
Welfare Administration
MAJOR PHS FIELD INSTALLATIONS
HOSPITALS
OUTPATIENT CLINICS
HAWAII AND ALASKA MATTERS
AREA OFFICES
FIELD OFFICES
HOSPITALS
HEALTH CENTERS
ARCTIC HEALTH RESEARCH CENTER
COMMUNICABLE DISEASE CENTER
FIELD STATIONS
DIVISION OF CHRONIC DISEASES
FIELD STATIONS
NAVAL MEDICAL RESEARCH UNIT
OCCUPATIONAL HEALTH RESEARCH AND TRAINING FACILITIES
ROCKY MOUNTAIN LABORATORY
SANITARY ENGINEERING CENTER
QUARANTINE STATIONS
SHELLFISH SANITATION RESEARCH CENTER
RADIOLOGICAL HEALTH OFFICES
NON-FOREIGN RESEARCH OFFICES
July 7, 1966

FIGURE 1

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The principal agency within HEW responsible for the provision of health care, and for financial assistance to State and local governments for health services, is the U.S. Public Health Service. The organizational structure of this unit is to be modified under the terms of the President's Reorganization Plan No. 3 of 1966, which became effective on June 25, 1966 (see appendix B). The present organizational structure of the Service is set forth in figure 2, and the proposed reorganization of the Service, pursuant to Reorganization Plan No. 3, is illustrated by figure 3.

A detailed description of the health functions and activities of the various agencies within the Department of HEW, including the Public Health Service, will be found in the subcommittee print entitled "Background Material Concerning the Mission and Organization of the Health Activities of the Department." This two-volume document was prepared for this subcommittee and printed in March of 1966. While the pending reorganization under the authority contained in Reorganization Plan No. 3 of 1966 will modify the structure of the Public Health Service, the subunits comprising the PHS will retain, for the most part, the responsibilities and activities described in the subcommittee print.

In considering the health service activities of the Department of HEW, it is important to bear in mind that the term "health services" generally is used with different meaning in referring to different categories of Americans. There are groups of citizens to whom the Government is committed for full medical care (e.g., military personnel and their dependents, eligible veterans of the U.S. Armed Forces, Federal prisoners, etc.). There are other health activities performed by HEW which have more general application to all citizens. The primary concern of this report is with the latter category.

It is difficult to arrive at a precise definition of the term "health services" since the term can include a great variety of activities. The term includes those programs and activities of the Department which support, either directly or indirectly, the actual delivery of health care to people. Examples are the specific health services project grants, such as the tuberculosis control and venereal disease control grants. Formula grants to the States for health services, such as the general health grants and the home health services grants are also included.

The importance of effective Federal-State-local dialogue and joint planning is much greater in the area of health services than it is in the area of pure research. The ability of a state or metropolitan health officer to administer a sound and well-balanced program does not require that he be consulted or informed about every basic biomedical research project being carried out in the universities in his State or city. This type of Federal support can be, and perhaps should be, removed from the sector of Federal-State-local joint participation. The need for close Federal-State-local coordination is critical, however, in the field of grants which support delivery of health services. Therefore, the construction of health facilities, conduct of screening

programs, nursing services, demonstrations, specific care projects, and the like should be carried on with the knowledge, cooperation, and appropriate participation of all levels of government if the best use of available funds and manpower is to be realized.

A line of mathematical precision may be difficult to draw in this area, but the subcommittee feels strongly that when Federal funds and authorities support the application of the fruits of scientific discovery for the benefit of the people, all levels of government must be mobilized in the activities of planning and implementation. When this is not done, duplication, waste, and inefficiency are inevitable.

The primary activity of the Department with respect to health services is not the direct provision of medical care to the people, but, rather, programs of financial assistance, consultation, demonstration grants, traineeships, and other forms of supportive assistance. These are designed to assist State and local authorities in strengthening their own health resources and programs. It is in the consideration of this effort that the subcommittee encountered a bewildering and confusing array of activities, organizational boundaries, and grants, all concerned with advancing the cause of health in some way. The subcommittee was impressed with the fact that the great mass of legislation, regulations, and interpretations of regulations, characterizing the HEW health-related financial assistance programs proved to be so complex and multifaceted as to confuse not only health authorities at the State and local levels, but even officials within the Department itself.

This has given rise to a new competence known as "grantsmanship"—the art of drafting the kind of project proposals most likely to find favor with the various agencies within HEW which administer the grant-in-aid programs. Practitioners of this art must learn also the techniques of negotiation and persuasion required to shepherd these applications through the various stages of administrative review leading to final approval.

In appendixes C, D, E, and F of this report, an attempt has been made to summarize the various grant-in-aid programs available from HEW with respect to the type of grant, the eligible recipients, and the "donor agency" within HEW which administers the funds.[15] It may be noted here that there are, in general, five different classes of recipients eligible for these various grant-in-aid programs: State agencies, local agencies, private nonprofit organizations, educational institutions, and individuals.

The grants, in general, are designed to support one or more of six different health-related activities: Research, training, services (formula), services (project), planning and construction.

[15] The following publications are recommended for a more intensive review of the numerous HEW administered grant-in-aid and other financial assistance programs:

"Grants-In-Aid and other Financial Assistance Programs administered by the U.S. Department of Health, Education, and Welfare", published by the Department of HEW (1966).

"To Improve Medical Care—A Guide to Federal Financial Aid for the Development of Medical Care Services, Facilities, Personnel." Published by the Department of HEW (April 1966).

"Catalog of Federal Aids to State and Local Governments" prepared for the Senate Subcommittee on Intergovernmental Relations (Apr. 15, 1964, with supplements dated May 17, 1965, and Apr. 6, 1966).

The grants are administered by many different units within HEW. The major donor units for health-related grant-in-aid programs are:

Office of Education:
Public Health Service:
- Bureau of Medical Services.
- Bureau of State Services (Community Health).
- Bureau of State Services (Environmental Health).
- National Institutes of Health.
- National Library of Medicine.

Vocational Rehabilitation Administration.
Welfare Administration:
- Children's Bureau.
- Bureau of Family Services.

The above-named subdivisions of the Public Health Service refer to the current organization of the PHS. The effect of the proposed reorganization, pursuant to Reorganization Plan No. 3 of 1966, will be to shift the responsibility for administering grant programs from the above units to their successor units in the new PHS organization.

Some grant-in-aid programs require matching funds while others do not. Among those requiring matching funds, the percentages required are not uniform. Some require prior approval of the grant application by the appropriate State authority while others have no such requirement. There also exists a diversity of forms which must be employed in applying for the various grants. The authorities with whom the subcommittee has been in contact during the past year were almost unanimous in deploring the confusion and inefficiency engendered by this system of fiscal support. Certain elements of this criticism will be discussed as part of the subcommittee's recommendations.

In recognition of the need for a more flexible and unified system of health services support by the Federal Government, identical bills, S. 3008 and H.R. 13197, were recently introduced in the Senate and House of Representatives. A significant change proposed in these bills would remove the health category limitations, except for mental health, of formula grants.[16] Instead of grants limited to special categories, annual block grants would be made in a single amount to each State to meet the health problems deemed most critical in that State. Each State thus would have greater flexibility in the use of Federal funds. The proposed legislation would also establish a State health planning council, which would include representatives of State and local agencies and nongovernmental organizations and groups concerned with health, and of consumers of health services, to advise the State agency in carrying out comprehensive health planning.

While not wishing to take a position concerning this proposed legislation prior to its being considered in formal hearings, the subcommittee does feel strongly that the removal of restrictions presently in effect requiring the limitation of certain funds to specified health categories would be a great improvement over the present system of categorized grants.

[16] Under this proposed legislation, 15 percent of each State's allotment would have to be used for mental health.

IV. Findings and Recommendations

The recent change in leadership at HEW has already been noted in this report. While the problems besetting the Department's support of health services are serious and long standing, the initiative presently characterizing HEW leadership is cause for optimism. Moreover, HEW is presently engaged in a serious reevaluation of its organizational patterns and programs.

Based on its study of HEW, the subcommittee makes a number of findings and recommendations which follow. The recommendations are not uniform in scope. Some are put forward as relatively minor measures which could be put into effect quickly by the Department. Many would serve merely as interim measures pending more comprehensive changes in the makeup and activities of the Department.

It is hoped that the following recommendations will be helpful to the Department in formulating its plans for the future. A beginning has been made with Reorganization Plan No. 3 of 1966, authorizing reorganization of the Public Health Service (see appendix B). In his message to the Congress accompanying this reorganization plan, the President stated: "As citizens we are entitled to the very best health services our resources can provide. As taxpayers, we demand the most efficient and economic health organizations that can be devised." We can, indeed, be satisfied with nothing less.

In order to bring home effectively to the American people the benefits of the scientific discoveries for which their tax dollars have been spent, the effective cooperation of all levels of government must be obtained. No one level of government, be it Federal, State, or local, can assume the entire burden of providing all the health services to which our citizens are entitled. Today, with hospital and supplementary health insurance for the aged through the social insurance system, and medical assistance payments for aged and other needy through welfare grants, the Government role has moved toward assuring to all citizens the availability and accessibility of high-quality medical care. There must, however, be full participation and cooperation of all levels of government in this endeavor if it is to be successful.

Recommendation A: There is a need to establish a single organizational focus of Federal health authority and responsibility; establishment of a Department of Health and a Secretary of Health; Under Secretary of HEW for Health

From the outset of its study, the subcommittee realized that unanimity of opinion could not be expected from the diverse experts, officials, administrators, and others whose opinions would be received during the course of this project. The views of these various experts have indeed differed in relation to, among other things, the profession of the expert, his official capacity, his personal political philosophy, and many other variables. Nevertheless, the subcommittee has found a surprisingly complete consensus on the need for a consolidation of Federal health activities and responsibility into a single organizational focus. There was less unanimity in the recommended methods for bringing about this consolidation, but the need for such action seems to be recognized by all. The most acute need for such consolidation is in the Department of HEW.

The question of consolidation of Federal health responsibility is complicated by the fact that so many Federal health activities are

carried out by agencies other than the Department of HEW; this will most probably be true for some time to come. It is appropriate that many Federal agencies are interested in health, and have health programs. In discussing "health programs," however, a distinction must be made between those agencies which have such programs as a means to the fulfillment of some other administrative mission, and those for which the health programs are a primary concern. An example of the former type would be the Department of Defense, whose purpose is to provide for the national security; a mission which, of necessity, involves the establishment of health programs to provide medical care and services to military personnel and their dependents. In contrast the Public Health Service is the Federal agency specifically charged with the responsibility of protecting and improving the health of the people of the United States. The health programs and activities carried on by the PHS are, therefore, not merely supportive of some other mission but are the very raison d'etre of the agency. The subcommittee's recommendation for consolidation of Federal health activity, therefore, refers to those federal activities which are directed toward health per se.

Even though fragmentation of health activity also exists at the level of State government,[17] there seems to be little question but that the most complex organizational picture in public health in the United States is to be found at the Federal level. In place of a single Federal health authority, there presently exists an illogical maze of miscellaneous departments, bureau, offices, agencies, commissions, services, and authorities, each with responsibility for one or several aspects of the Federal Government's concern with health.

The dimensions and character of this fragmentation, and the problems arising from it, were the subject of three papers prepared by participants in the subcommittee roundtable discussion on the Federal-State-local health partnership, held on April 21–22, 1966.[18] In commenting on this problem, Surgeon General Stewart told the subcommittee:

> Mr. Chairman, the description of the problem which the papers gave this morning, I think, is quite accurate and very clear. The problem has been with us for a long time. It is described in the literature for 25 years. It is also described as an increasing problem in the literature. * * * I think more important is what do we do about it? How do we get from here to where we want to go? First, is where do we want to go? What are we really trying to do which, as an end point, will end up with better health services for people? I believe that health programs will be in many agencies for some time to come. But I believe also that there should be one agency which has the health of the people as its sole responsibility and objective. The problem, it seems to me, is to make sure that one always sees clearly what is the objective of a certain program, and how do the health functions of that program fit into that objective.[19]

Similar sentiments were expressed by the large majority of experts who testified before the subcommittee and who were consulted during the course of the study. Recommendations for accomplishing a unification of Federal health authority were numerous, including establishment of a separate Federal Department of Health.

After carefully reviewing the testimony and other evidence before it, the subcommittee concurs as to the desirability and necessity of

[17] See "The Problems of Fragmentation of Community Health Services," by Ben Freedman, M.D., M.P.H.; Medical Times, January 1964.
[18] Hearings, pp. 197–221.
[19] Hearings, p. 218.

establishing a Department of Health, to serve as a central focus for Federal health authority and responsibility. In view of the growing interrelationships between the Nation's health programs and its education and welfare programs, the subcommittee feels that such Department of Health should be located within HEW, however. The subcommittee therefore recommends that the Department of HEW initiate steps to establish a separate Department of Health within HEW, headed by a Secretary of Health. In this connection, the subcommittee noted with interest the recent testimony of Secretary John Gardner before one of our sister committees, wherein he stated:

> Various proposals have been put forward for upgrading the Office of Education without actually separating it from HEW, and I think these deserve serious discussion. It has been suggested, for example, that we have an Under Secretary for Education. It has been suggested that we make HEW a Pentagon-type superdepartment with three Secretaries reporting to one overall Secretary. I see no reason why we should not examine such possibilities.[20]

After its year of study into the health programs of the Department of HEW, it seems to the subcommittee that there is a pressing need for more coordination and unified authority for health activity at HEW. The proposals for upgrading the education functions of HEW, discussed above by the Secretary, apply with at least equal force to the upgrading of the Department's health functions.

In addition to establishment of a Department of Health, and as a possible preliminary step thereto, the subcommittee recommends that an Office of Under Secretary of HEW for Health be established as soon as possible within the Department. This Under Secretary would report to the Secretary of HEW and would have line authority over, and responsibility for coordinating, all health and health-related activities of the Department. Similar offices of Under Secretary of HEW for Education and for Welfare also should be established, in which event it would appear desirable to change the title of the present office of Under Secretary of HEW to "Deputy Secretary of HEW."

Along with the need for an Under Secretary of HEW for Health to coordinate the health functions of the Department, there is a need for an organizational consolidation of the health programs presently carried on by several agencies within HEW. The absence of a single Federal agency having responsibility and authority over health matters, and the desirability of instituting one, have been recognized for many years.

In a report to the Congress dated March of 1949, for example, the Hoover Commission recommended the reorganization of Federal medical activities under a proposed United Medical Administration:

> Only the creating of a new United Medical Administration can remedy the weaknesses of the present organization and give the leadership, direction, and planning urgently needed. To it would be transferred the Government's major services in the field of medical care, public health, and medical research.
>
> The Nation's vast medical services, which we have noted lack any central plan of operation, require unified responsibility. The Government must have a central plan if waste and inefficiency are to be avoided.[21]

Similarly, in his testimony during the joint hearing before the Committees on Government Operations of the House and Senate con-

[20] Statement of Hon. John W. Gardner, U.S. Department of Health, Education, and Welfare, before the Special Subcommittee on Education of the Committee on Education and Labor, U.S. House of Representatives, Tuesday, Aug. 2, 1966.

[21] "Medical Services—A Report to the Congress," U.S. Commission on Organizing of the Executive Branch (March 1949), p. 15. Three Commissioners dissented from the recommendation on the basis that the Government's medical functions should be administered within the same organizational structure as the education and social security functions. Id., p. 41.

sidering Reorganization Plan No. 1 of 1953, which established the Department of Health, Education, and Welfare, the representative of the American Medical Association expressed a certain amount of reservation at the inclusion of health functions within the new Department. He noted that the AMA had for nearly 80 years been on record as favoring an independent Department of Health in the Federal Government.[22] The American Medical Association recently reaffirmed its position by adopting a resolution calling for a separate Cabinet post to administer federally sponsored health programs.[23]

While there is certainly much to be said in favor of the various proposals which have been putforward from time to time for a separate Cabinet-level Department of Health, the subcommittee does not feel that efficient administration and effective leadership for Federal health activity require the setting up of an independent Department for this purpose. The goal can be largely realized, the subcommittee feels, by identifying the programs of the Department of HEW, wherever found, which are primarily health services programs, and subjecting them to the authority and control of the proposed Under Secretary of HEW for Health, until such time as a Department of Health can be established within HEW. As many of these programs as possible should be transferred to the Public Health Service, which should be expanded in scope so as to constitute a true Federal health authority. The reasons in favor of such an organizational consolidation of Federal health authority were well stated by Dr. Herman E. Hilleboe of Columbia University, the moderator of the roundtable discussion held before the subcommittee:

> It is obvious there is a need for a principal health agency in government. Unless someone can come up with a better agency, it should be built around the Public Health Service. Whether we turn it into a Health Administration, whether we call it something else, we really need to have a principal health agency in the Federal Government, preferably in Health, Education, and Welfare, because this is the area of human resources. * * * (I)t is necessary to have it, because we have to have one group responsible for policy and for planning; not for HEW, but policy and planning for the United States of America.[24]

As has already been stated, there are many Federal health activities administered by agencies other than HEW. Some of these have been referred to in the above-quoted testimony. If there is to be effective coordination of Federal health activity and efficient utilization of health manpower, the proposed Under Secretary of HEW for Health must be given responsibility and authority to coordinate the health activities and programs of HEW with the health activities and programs of Federal agencies and departments outside HEW.

Under the present conditions, such coordination is most difficult. It is noted that most of such coordination now comes about through a cumbersome system of interagency committees related to health activities. Appendix A, part C, of this report contains a list of approximately 50 of the major interagency committees, subcommittees, task forces, and so forth, engaged in attempting to coordinate the related health programs of the Federal Government. These interagency committees vary in both scope of subject matter and membership.

[22] "Reorganization Plan No. 1 of 1953—Joint Hearing Before the Committees on Government Operations of the House of Representatives and Senate of the United States (Subcommittee on Reorganization)" 83d Cong., 1st sess. (Mar. 16, 1953), p. 90.
[23] Proceedings, AMA House of Delegates, Nov. 28–Dec. 1, 1965.
[24] Hearings , p. 344.

The list includes, for example, the Advisory Safety Committee on Farm Employed Youths, whose function is to "reduce the number of deaths and injuries occurring to minors under 18 years of age who are employed as paid workers on farms." Another group is the President's Committee on Employment of the Handicapped (Medical Committee), whose function is to "conduct information programs to impress employers and physicians with the concept of the whole worker, his physical environment and the ability to perform occupational tasks in business and industry despite physical irregularities."

The subcommittee feels that some more comprehensive and unified administrative technique must be found to better coordinate the vast amount of activity being carried on by the Federal Government in the field of health. No single interagency committee can be found whose membership includes all of the principal agencies in the Government that have health responsibility, and whose function includes a review of the entire Federal health effort.

In view of the very large sums being expended in these various programs, and the ever-increasing danger of overlap, duplication, and working at cross purposes, the Subcommittee recommends the establishment of a Federal Interagency Committee on Health.[25]

Such a committee would draw its membership from all of the agencies of the Federal Government having substantial health activities. It would take precedence over the various specialized interagency health committees presently existing, and, furthermore, should replace as many of them as possible. With the proposed Under Secretary of HEW for Health acting as its chairman, it would have the difficult task of monitoring and reviewing the entire Federal health effort. The representatives of the various Federal agencies, therefore, should be highly placed officers whose membership on the Council would be one of their main activities.

In summary, the Federal house must be put into better order. It cannot realistically be expected that State and local jurisdictions will be able to coordinate their services and plan community health programs on a sound basis if this is not done. The American people deserve, and will sooner or later insist upon, a more organized and rational approach to governmental health activities. Before the American public can effectively require of their various levels of government a satisfactory performance of governmental health functions, someone must be in charge and accountable.

RECOMMENDATION B: THERE IS A NEED TO DEVELOP COMPREHENSIVE PLANNING FOR THE NATION'S HEALTH EFFORT; ESTABLISHMENT OF A NATIONAL HEALTH COUNCIL

One of the most surprising facets of Federal health activity to come to light during the subcommittee's study is the fact that there presently exists no comprehensive health planning at the Federal level. While the Nation has been committed to the task of providing the best possible health care for all citizens, there has been no comprehensive strategy or plan formulated for accomplishing this. Basic questions still remain unanswered as to the proper scope and balance of public as opposed to private medicine, of public health departments as opposed to rehabilitation and welfare departments,

[25] A Federal Interagency Committee on Education already exists, with the HEW Assistant Secretary for Education as Chairman ex officio.

and, perhaps most important, of Federal, as opposed to State, as opposed to local governmental authority and responsibility in health matters.

In one sense, there is no shortage of "plans" in the health field. Each State must submit many plans each year to the Public Health Service in justification for Federal grants to support various health activities. Plans must be submitted to the National Institute of Mental Health, for example, to qualify for Federal funds for community mental health centers. Plans must also be submitted in connection with the Hill-Burton program for hospital construction, for mental retardation programs, vocational rehabilitation programs, crippled children programs, and many more. There has been, however, no concerted attempt to formulate a comprehensive health plan for the Nation as a whole outlining the proper functions of the various levels of government, and the agencies of each, in supplying health services to the people. In this connection, it is relevant to quote from the President's message on health and education of March 1, 1966:

> The focus of our efforts is the individual and his family living in their own community. To meet their health needs requires the cooperation of many agencies, institutions, and experts—of State and local government, of doctors, nurses, and paramedical personnel.
>
> These are the frontline fighters in our battle against disability, and death. As in military battle, a winning strategy demands wise and well planned use of manpower. It demands coordinated use of all the resources available.

It seems unrealistic to expect a "coordinated use of all the resources available" without health planning and evaluation on a national basis. No successful military campaign can be prosecuted without a sound strategy, and sound tactics to implement it. A decisionmaking chain of command must exist. Areas of responsibility must be established and understood by all, and assessment must be made as to the numbers, strength, weaknesses, and capabilities of the subunits constituting the total available force. The struggle against disease and substandard health must be fought with different weapons and forces. Nevertheless, an effective struggle cannot be waged without answers to the basic question indicated above.

As mentioned previously, there is before the Committee on Interstate and Foreign Commerce proposed legislation designed to promote comprehensive health planning at the State level.[26] There is no similar provision imposing the same duty to plan on the Federal Government itself. The need for a more effective Federal-State-local health partnership will not be met without an understanding being reached as to the participation, rights, and duties of the partners. Confusion, duplication, fragmentation, and the absence of coordination and planning in the administration of health programs place the objectives of Congress, and the welfare of the Nation, in jeopardy. The formulation of a comprehensive strategy for the Nation's health effort would work as an advantage to all present Federal agencies by delineating their areas of responsibility and activity. It would serve as a yardstick by which the Congress could measure proposed new legislation. The ultimate advantage would be to the Nation as a whole in the assurance that the limited health resources, both money

[26] S. 3008 and H.R. 13197, "Comprehensive Health Planning and Public Health Services Amendments of 1966."

and manpower, would not be wasted in needless duplication or competition.

The formulation of such a far-reaching and comprehensive plan, and the periodic review and reevaluation which will be necessary once it is in being, require more than the familiar ad hoc panel of experts which meets briefly, issues an impressive report, and disbands. The initial formulation of the plan which the subcommittee recommends cannot be accomplished without extended deliberation by a council which is national in scope. If such a council is to have any real effect in bringing together the Nation's health efforts, it must be composed of representatives of all governmental units who have responsibility for providing health services. This will entail the presence of representatives from the various Federal agencies, including HEW, which have substantial health programs. Representatives must also be present who have authority to speak for the various State government units having health responsibility. County, municipal, and regional health officers must also have their representatives. In short, the National Health Council must involve an in-depth deliberative process with participants who are the representatives of all those various governmental units which have health authority and responsibility.

Representatives of private medicine and dentistry, and of the academic world, must also participate and make their contributions. The importance of including representatives of all those who have been entrusted with official governmental responsibility for health programs is paramount, however. Congress might also have representatives present at the Council.

The subcommittee is well aware of the considerable administrative problems involved in convening such a national health council, and the problems involved in reconvening such councils (perhaps on a smaller scale) for the necessary periodic review of the strategy of the Nations health effort. If a truly comprehensive plan is at long last to be put into effect, however, it cannot be done without a major effort. It will not be sufficient to merely gather together for a 2- or 3-day conference a selected group of public health experts whose recommendations will be perpetuated in still another impressive report which will find its place on the shelf beside the multitude of previous impressive reports which have gone before. We have had no lack of conferences, councils, meetings, hearings, workshops, and the like, addressed to various small pieces of the national health effort. Yet, the Nation is still left with competing governmental agencies administering piecemeal programs, competing with one another for scarce medical personnel, duplicating services in some areas and leaving services unperformed in others. Present medical technology permits us to aspire to new goals of disease prevention, health maintenance and longevity. These goals cannot be met without drastic improvement in the planning processes by which the health efforts of the different levels of government are directed. In this, the subcommittee adopts the statement of Dr. James L. Dennis, director and dean, University of Oklahoma Medical Center:

> I am expressing a considered opinion when I say that confusion, duplication, fragmentation, and the absence of coordination in planning and administering health programs places the objectives of Congress, and the welfare of this Nation, in jeopardy. I suggest that we mobilize the best brains of the Nation to plan a

charted course, and that we man our ships with an organized and disciplined crew before we set sail. At the moment it would appear to be "full steam ahead"—without pulling up the anchors. We can do better, and that we must.[27]

Before concluding this recommendation, it seems advisable for the subcommittee to emphasize that, by suggesting the formulation of a national health strategy or plan, it does not mean to enter into any field of controversy with respect to the proper dividing line between private and public medicine. But public medicine, whatever its scope, should be carried on within a rational framework of shared governmental and organizational responsibilities, and with clearly defined jursidictions and objectives. We do not have this rational framework, and it is badly needed.

In summary, the efforts being made at various governmental levels to provide health services seem to be proceeding on an unplanned, and sometimes almost chaotic, basis. The Nation's commitment to better health cannot be realized without a more effective utilization of the Federal-State-local partnership. Basic decisions must be reached and agreed upon by the members of this partnership as to the conduct of the national struggle against disease and substandard health.

RECOMMENDATION C: THE FEDERAL-STATE-LOCAL HEALTH PARTNERSHIP SHOULD BE STRENGTHENED

"Partnership" in the usually accepted sense of that term implies that the members of the partnership participate in an agreed upon manner in the decisionmaking and management of the enterprise. Under this definition, it must be frankly stated that there is no partnership among the various governmental units engaged in supplying health services to the people. In view of the lack of any definitive strategy for the Nation's health effort (see recommendation B), this result is, perhaps, inevitable. Yet, the fact remains, and was reaffirmed during the subcommittee's study, that no single level of government is equipped to preempt all governmental health care functions. As stated earlier in this report, the provision of health care and health services to the people demands coordination of all governmental levels if it is to be carried on successfully.

As a result of the lack of a real partnership, or working together, between the various levels of government, many State health officers complained to the subcommittee that there have been increasing direct contacts between the Federal Government and local governments in initiating health programs. Due to the fragmented nature of the Federal agencies dealing in health matters, this has led to the support of isolated groups whose programs may be planned without reference to other related community endeavors or to the programs being carried on by the State health department. Different demonstrations in the same general fields may be supported by several Federal agencies, and even different branches of the same Federal agency. This practice has led to federally sponsored competition for the same personnel, with the project offering the higher salaries for the longer duration winning out in the competition, instead of the preference going to the most significant project. This result may be explained, in part, by

[27] Hearings, p. 201.

the difference in viewpoint which exists between State and Federal health officers:

> The concern of the State health agency regardless of the breadth of its responsibility, is for total health planning, and when a grant, whether it be a project grant or another type of grant, bypasses the State planning agency, the one which is responsible, it destroys any mechanism for [a] comprehensive statewide jurisdictional health plan.[28]

Due to the fragmented nature of the Federal health authority, no single Federal officer is responsible for truly comprehensive planning of all health services on a nationwide or statewide basis. The Federal health authority dealing with a State health officer is more likely to be the representative of a particular grant program for limited health service activity. Having responsibility for promoting the success of his particular Federal program, the desire naturally arises on the part of the Federal health representative to control, as much as possible, the means by which the desired ends are to be accomplished. While such a point of view may be defended on the limited basis of achievement of statutory objectives, it has resulted in a disruption of the State health officers' ability to carry out their own responsibilities within their States.

Another factor tending to promote the practice of bypassing State health officers in making direct contacts to regional, county, and municipal health departments, is the fact that most health officers, be they Federal, State, or local, are men of similar academic backgrounds and interests. The Federal health officer, no less than his State or local counterpart, seeks to become involved at the delivery point of health services, and take an active role in "getting the job done." Dr. Bernard Bucove, State health officer of Washington, and president of the Association of State and Territorial Health Officers, addressed himself to this point in his testimony before the subcommittee:

> The bypassing of the State health authority does take place, and many annoying instances can be cited. Apart from the suggestion that competition between Federal agencies may be a factor here, I see this as primarily a result of an abiding desire on the part of people to get a job done, to get as close to the problems as possible, and to be able to demonstrate and feel a direct relationship between their activities and the successes achieved.
>
> I sympathize with them. I feel the same way, but I feel it is a self-defeating approach in solving most public health problems.[29]

In a sense, the recommendation which the subcommittee is now making would probably not be necessary if there existed within the Federal Government a single agency which was responsible for the health of all the people and an understood national strategy or policy which delineated the roles which the various levels of government were to play in supplying health services to the people. The implementation of these measures, recommended above in subcommittee recommendations A and B, would help to end the present competition between overlapping Federal agencies and between these Federal agencies and their State counterparts.

To be realistic, however, whatever organizational and administrative rearrangements may be undertaken, and whatever ground rules may be agreed upon, much will still be left to the discretion of the various Government officials responsible for the national effort in

[28] Statement of Dr. John H. Venable, director, Georgia Department of Public Health; hearings, p. 25.
[29] Hearings, p. 183.

bettering the people's health. This being the case, the promotion of a better partnership between the Federal, State, and local health departments cannot rest on the measures proposed in subcommittee recommendations A and B alone. There must also be a willingness on the part of all levels of government, and their representatives, to work together, and a much more meaningful and serious dialog among them, if real progress is to be made. This is the thrust of the recommendation which the subcommittee is now making.

The need for an improved dialog, however, is not confined to the Federal-State portion of the partnership; there also is much room for improvement in the State-local sector. The vast majority of people in the United States live in or around metropolitan areas. These metropolitan areas may involve several municipalities, several counties, and, in some situations, more than one State. In each of these metropolitan areas, or complexes, there is usually a central or core city which is the industrial and economic center. Unfortunately, it also is usually the center of social and health problems including disease, poverty, poor housing, crime, and all of the other problems with which the Nation is becoming increasingly concerned. New York City, which has 5 percent of the Nation's population, has 9 percent of the Nation's tuberculosis. The problems confronting the municipal health authorities are, therefore, of a serious and complex nature. The health problems of some municipal complexes have a greater magnitude then those of some States. The health director for the city of Detroit, Mich., for example, is responsible for the health of more people then well over half of the States contain.

Under these circumstances, some direct contact between the Federal Government and local governments is desirable and even necessary. Such direct communication, however, in the opinion of the subcommittee, need not and should not be an exclusionary process whereby the State health authority is denied its appropriate measure of participation. Unfortunately, many of the Federal-local contacts characteristically bypass the State health authority completely. Dr. John R. Philp, director of health for Kansas City, Mo., addressed himself to this problem:

> [U]nless the State, in every respect, recognizes the urgency of the need and the concentration of the health problems in metropolitan areas and correspondingly redesigns its own program to assist in planning and meeting these problems then it will be necessary more than ever for the Federal Government to develop a direct and simple method of dealing with the major and metropolitan areas in this country. These areas are literally the melting pots of disease and social problems.[30]

In this connection, Dr. Philp pointed out that, although Kansas City contains approximately 12 percent of the total population of the State of Missouri, it receives only 4 percent of the Federal grant-in-aid funds received by the State of Missouri.

Some of the present difficulties hampering the Federal-State relationship in health matters are undoubtedly quasi-historical in nature. After World War II, dispersion of health programs from State health departments to other agencies began within the States. In part, this proliferation was caused by new laws enacted by the Congress, and regulations of the Public Health Service. The PHS did not strongly encourage health program consolidation.

[30] Id., p. 211.

But these were not the only causes of the proliferation of health programs and the consequent deemphasis in the prestige of the State health departments. It must be frankly stated that many of the difficulties originated with the State public health administrators themselves. In many instances they failed to accept programs offered to them, thrusting them on other agencies rather than alter their traditional concepts of the scope of public health. Mental health is a foremost example of such a failure. One State health officer told the subcommittee:

> I sat in the office of one antiquated hidebound administrator who turned down the offer of funds to begin a mental health program because, "It's not public health." [31]

The State health officials who communicated with the subcommittee, while in most cases conceding that some of the difficulties in the Federal-State health partnership are in part the result of past policies of some State health administrators, nevertheless felt that the problems cannot be solved by merely bypassing the State health departments. Past difficulties in the operation of the Federal-State-local health partnership should not result in the elimination of one of the essential partners. It would be a great loss to the national effort to improve the peoples' health if failure to exercise leadership in the past were used as a rationale for denying to the State health departments the opportunity to exercise leadership in the future.

The subcommittee, by pointing out these past shortcomings on the part of State health departments, does not wish thereby to place undue emphasis on them, or to suggest that they were typical of State health departments generally. In fact, some of the older health-related programs, such as hospital construction and planning, have functioned well and demonstrated the advantages to be gained from full State participation.

What the subcommittee does wish to emphasize is that, regardless of the origin of the present difficulties in the Federal-State-local health partnership, there should be an earnest attempt by the Department of Health, Education, and Welfare in general, and the Public Health Service in particular, to eliminate the problems. The elimination of these problems will not come about, the subcommittee feels, by an increased tendency to bypass State health departments by the Federal Government. This would only lead to the eventual atrophy of State health departments; they cannot be expected to maintain their capabilities without being given the opportunities to exercise them. As noted by Under Secretary Cohen in his testimony before this subcommittee:

> Unless we are prepared to vastly strengthen the State health departments to meet this commitment we are not going to carry out all this wonderful legislation you enacted last year and the other proposals that we have pending before you this year.[32]

RECOMMENDATION D: THE PUBLIC HEALTH SERVICE ACT SHOULD BE REVIEWED AND RECODIFIED

In the opinion of the subcommittee, there has long been an urgent need for a simplification and recodification of the Public Health Service Act. This need has become even more imperative with the

[31] Id., p. 255.
[32] Id., p. 321.

taking effect of Reorganization Plan No. 3 of 1966 for the reasons set forth below.

Prior to 1944 a large number of provisions relating to the functions of the Public Health Service were scattered among various Federal statutes. In 1944 a revision and consolidation of many of these provisions into a single Public Health Service Act was enacted by the Congress.[33] Since 1944 the act has been amended frequently, placing responsibility for numerous additional programs in the Department of HEW and the Public Health Service. Other programs administered by the Department and the Service such as, for example, programs relating to clean air, solid waste disposal, and Indian health services, have been enacted as separate statutes.

One of the results of this process has been a continuing increase in individual, usually narrowly defined, and frequently duplicating, Federal health-related programs. A situation has been reached in which it is increasingly necessary to employ experts to keep track of the constellation of health-related grant-in-aid programs. The complexity and difficulty of the problem of keeping abreast of the available Federal health grants must partially explain the immense popularity enjoyed by official publications which seek to explain and condense the legislation relative to Federal grant programs. One of the most popular of these, for example, is a committee print of the Senate Government Operations Committee entitled "Catalog of Federal Aids to State and Local Governments," prepared by the Library of Congress. Approximately 100,000 of these catalogs, including supplements bringing the listing up to date, have been distributed. This listing includes grants other than health related, but they account for a large percentage of the total grant programs described in this listing.

A recodification of the PHS Act would afford an opportunity to simplify and condense the sections presently covering health-related grant-in-aid programs. The present time seems particularly appropriate for such a review, since the President's Reorganization Plan No. 3 of 1966, which became effective on June 25, 1966, has had the effect of repealing the present section 202 of the act. This section sets forth a required organizational pattern for the Service, stipulating that it shall consist of the four major components listed therein. These components, however, have now been abolished by the reorganization plan.

A recodification at this time also would afford an opportunity to correct the various discrepancies which presently exist in the percentage of matching funds available to State governments under different programs of essentially the same importance. Similarly, and by way of implementing subcommittee recommendation A for a consolidation of Federal health authority, health programs presently administered outside of the PHS might be considered for inclusion into the new Public Health Service Act. Just as the subcommittee has recommended an administrative consolidation f Federal health authority, so it now recommends that the legislation governing Federal health activity be redrawn and simplified.

[33] Public Law 410, 78th Cong., 58 Stat. 683.

RECOMMENDATION E: CLOSER COORDINATION IS NEEDED, AT THE DELIVERY POINT OF SERVICES, BETWEEN MENTAL HEALTH ACTIVITIES AND THOSE INVOLVING GENERAL PHYSICAL HEALTH

On December 29, 1959, the Surgeon General of the Public Health Service announced the formation of a study group on the mission and organization of the Public Health Service. The charge to the group was to study the present, and the probable future mission of the Public Health Service over the next decade; then to design the best possible organizational structure to accommodate the present and future responsibilities. The Group's recommendations on organization were contained in the "Final Report of the Study Group on Mission and Organization of the Public Health Service (1960)" (Hundley report). One of the conclusions reached by this group was that the National Institutes of Health should be restructured so as to exist primarily as an organization to conduct and support biological and medical research. It was the conclusion of the group that the disease control and health services functions then performed by the various Institutes should be withdrawn from them and associated with other parts of the Public Health Service:

> The conclusion reached in this study was that the central mission of the Institutes should be research, and that the only additional activities to be retained should be those immediately supportive to that role, i.e., research manpower and research facilities. This will permit the Institutes to concentrate even more effectively on their research mission. At the same time the nonresearch functions to be transferred would strengthen other parts of the Service, and place these programs in an environment where they can flourish and grow in an association with other like programs (p. 44).

The disease control and health services functions were, accordingly, removed from the National Institutes of Health and placed with the Chronic Diseases Branch of the Bureau of State Services of the Public Health Service.

An exception was made, however, in the case of the National Institute of Mental Health. Control of its demonstration and technical services functions was not transferred to the Bureau of State Services. In addition to conducting laboratory and clinical research programs, therefore, the NIMH continued to administer programs of demonstrations and technical services to States and communities, generalized training of mental health and related personnel, and, more recently, grants-in-aid for community mental health centers.

Under the terms of the recently announced reorganization plan for the Public Health Service, the National Institute of Mental Health will be detached from the National Institutes of Health and set up as a separate new Bureau of Mental Health. Organizationally, therefore, the mental health "service" activities of the Public Health Service have been distinct from the general physical health activities. The new reorganization setting up the separate Bureau of Mental Health will further emphasize this distinction.

This trend has also been reflected downward into the State organizations. In only eight States (including the District of Columbia) are the institutions for mentally ill and retarded under the authority of the State health department or board. In an additional five States, and Guam, this authority is placed with the State department of health and welfare. In 24 States, this authority is placed either with an autonomous department of mental health or an independent board

responding directly to the Governor. This separation of mental health activities seems to be the trend among the State governments. It is clear that there has been an increased awareness of mental health problems by both the State and Federal levels, and that this has been reflected both in the administrative structures and the appropriations with which these levels of government have responded.

In the opinion of the subcommittee, this increased emphasis on mental health and awareness of mental health problems in the United States should not obscure the basic fact, emphasized by many experts who communicated with the subcommittee, that at the point of delivery of health services, mental health cannot long be considered a distinct and separate concept from the general health of an individual. Many echoed the sentiments of Dr. Joseph Cannon, Rhode Island Health Director:

> Quite frankly, I feel that mental health is a part and parcel of total health, that the psychiatrist is a physician and that mental health has really been separated from the main stream of medicine too much already. I do believe that the community mental health program should be a part of the total health program. I can't conceive of a separate mental health clinic or building which I have heard of, where there is also a public health building. I cannot conceive of a mental health nurse going into the families—we are going right back to the categorical approach, when there were public health nurses there. As much as possible a community mental health program, I would think, should be tied in with the mainstream of public health service.[34]

The subcommittee recommends that every effort be made to tie in more closely the fields of mental and physical health.

Probably the most striking administrative separation of health programing has occurred in the mental health field. This has developed largely because of the type of Federal funding for mental health programs and the concurrent administrative requirements for the receipt and use of funds. The net result has been to create what has been called "a separate but equal" health agency for mental health to parallel the health agency for physical or public health.[35]

This is not meant to minimize the urgency of the mental health problem in the United States. Figures presented to the subcommittee indicate that there are still 19 million people in the United States who need attention for mental or emotional problems; one out of over three families is affected.[36] It is understandable that the Nation has felt a certain urgency in promoting a number of mental health and mental retardation programs. As a result, however, facilities becoming available for community mental health centers may tend to outstrip those available for general physical health.

In view of the advantages in treating an individual's problems at one location, and simplifying the process of obtaining services, the subcommittee recommends that the Public Health Service take the leadership in effectuating an integration of community facilities providing service to the mentally and physically ill. This recommendation is directed to the subject of clinics, centers, halfway houses, and similar installations. In a sense, the recommendation which the subcommittee is making on this point follows a historical trend which has been operating to bring mental health programs closer together with the general field of public health. The development of mental

[34] Hearings, pp. 15–16.
[35] Id., p. 209.
[36] Id., pp. 262–263.

health was primarily as a hospital-operating department as a State service. Public Health, on the contrary, started with community programs. It has only been fairly recently that the departments of mental health have developed community programs and departments of public health have developed hospital programs, "so that originally where we were quite separate and there was no real problem of duplication, now we overlap in many areas." [37]

The subcommittee has serious misgivings as to the desirability of establishing a separate Bureau of Mental Health within the Public Health Service, which would appear to reverse the trend toward amalgamation of mental health and physical health. The subcommittee strongly recommends, therefore, that the Department undertake a detailed review of the operations of the Bureau of Mental Health approximately 1 year after its establishment, with a view to determining whether its separate status is compatable with an effective integration of physical and mental health services at the local level.

Even if an organizational merging of mental and physical health administration is not deemed necessary, the need for joint planning is evident. This joint planning should, incidentally, also include public welfare and rehabilitation. It is believed that, due to the substantial sums available for community mental health activities, the integration of mental health and public health activities at the local level will produce an immediate increase in the quality of public health services. This thought was expressed in another way by Dr. Herman E. Hilleboe, the moderator of the round-table discussion held before the subcommittee on April 21–22, 1966:

> In other words, at the service level if you had your public health clinics so that the people could come to the same place this really is something which would have great influence. Actually, it is rather interesting that here we are asking mental health to let public health get on its coattails because of the big funds for centers.[38]

RECOMMENDATION F: THERE IS A NEED TO ESTABLISH A CENTRAL CLEARINGHOUSE FOR HEALTH SERVICE GRANT APPLICATIONS AND STANDARDIZED FORMS FOR APPLYING FOR SUCH GRANTS

Anyone reading over the complex legislation and interpretative regulations governing the various "service" type grant programs (as distinguished from "research" grants) administered within the Department of HEW will be impressed by their complexity. Some idea of the extent of this complexity can be gained by reviewing the material presented in appendixes C and D of this report which list the various grant programs, indicate the donor agencies within HEW, the possible recipients, and the required forms.

It is also necessary to bear in mind, however, the further complication which arises from the fact that the various grant programs are administered by different officials within HEW whose personal interpretations of the governing legislation and regulations must also be taken into account by the applicants for these grants. In this area, rather than assisting the State and local governments to make the best use of their available health manpower, the Federal Government may have served as a roadblock to effective manpower utilization. State health officers from all parts of the Nation complained of the inordinate amount of time, measured in valuable man-hours of effort by trained

[37] Id., p. 273.
[38] Id., p. 273.

personnel, which are now required to prepared, justify, negotiate, revise, and otherwise manipulate these grant applications. As has already been stated above in recommendation C of this report, a permanent solution to these difficulties must, of necessity, include a more viable Federal-State-local partnership characterized by mutual respect and recognition of the interdependence of these levels of government.

Recognizing that the above-mentioned recommendation cannot be effectuated immediately, the subcommittee suggests that, as an interim measure, HEW designate a central clearinghouse for all incoming applications for health services grants, and devise a standard form for such applications. The various standards required for health care and services under the various existing grant programs should be brought into conformity. The subcommittee can see no justification for the imposition of varying standards for programs dealing with the same general subject matter.

A standardized procedure would ease the administrative task of health officials dealing with the Federal Government. The serious short supply of medical personnel at the State and local level forbids the luxury of involving these scarce individuals in unnecessary, and oftentimes artificial, administrative operations:

> A tremendous amount of increasingly very scarce and very expensive professional time could be saved by simplifying and standardizing the format of these grant requests and progress reports and * * * by a greater trust in the responsibility, of State and local health officials, which are watched assiduously by the public community groups, and others.[39]

Concern over this problem was found to be widespread by the subcommittee. The Honorable Marion B. Folsom, chairman of the National Commission on Community Health Services, and former Secretary of Health, Education, and Welfare, for example, testified:

> The greatest need in connection with the other grant-in-aid programs is better coordination in their administration. There have been so many new programs introduced providing grants for demonstration projects, experiments, planning and research into various health and mental health fields that it is very difficult for public health officials, voluntary agencies or individual health people to keep informed or to know to whom application should be made.
>
> * * * Should there not be one point which could serve as a clearinghouse and coordinator for all the small, miscellaneous grant programs, so that everyone would know to whom to go?
>
> Should not a plan also be developed to have local applications clear through the Public Health officer? It would also seem that all applications from a State should clear through the State health officer. Such a system has been successful in connection with applications for grants under the Hill-Burton program.[40]

On this latter point raised by the former Secretary, it is noted that legislation presently before the full committee will impose upon the State the requirement of setting up a central comprehensive planning body through which all outgoing grant applications must be cleared. The recommendation which the subcommittee now makes does no more than to suggest that the Federal Government, too, might profit from such a simplification of grant application activity. The present system, requiring that grant applications be sent to a number of different locations within the HEW framework seems to be inconsistent with the unity which exists in the health problems encountered at the local level; these do not lend themselves to compartmentalization

[39] Statement of John H. Hanlon, M.D., commissioner of health, Detroit, Mich.; hearings, p. 75.
[40] Hearings, pp. 100–101.

and separate treatment. An individual with 10 health problems must still be treated as an individual, not as 10 individuals, each with 1 problem.

The type of activity which the subcommittee feels should be avoided in the future is typified by an instance related to it:

> In one State, a psychiatric institute of a university had to file three separate applications for three related parts of a new construction. They received three different site visits from three different teams of Federal personnel. It is clear in this instance that thousands of dollars were wasted. It also tends to strain the relationships between Federal and State personnel because of the seemingly senseless activity into which they are forced.[41]

A central HEW reviewing office for all incoming grant applications for public health and health service activity would afford the most efficient and convenient method by which HEW could establish priorities among competing grant applications based upon a realistic appraisal of the individual State's or community's resources. This would avoid the real danger of having Federal funds finance simultaneous projects in the same State or community which compete with each other for scarce medical and paramedical personnel.

To summarize, the subcommittee recommends that there be established a centralized and uniform system, including forms, for all incoming applications for health services grants. The institution of such a central clearinghouse would correspond to the similar requirement imposed upon the States under the terms of the presently pending legislation H.R. 13197, to set up a single State agency for comprehensive State health planning. Such a system, if established at both the State and local levels, would approximate the administrative channels presently existing in the area of hospital construction grants under the Hill-Burton program.[42]

RECOMMENDATION G: THE RESTRICTIONS PRESENTLY PLACED ON THE ACTIVITIES OF PUBLIC HEALTH NURSES SHOULD BE MINIMIZED OR ELIMINATED

Another drawback to the present system of fractionalized health authority and grant-awarding procedures was noted by the subcommittee. This has to do with the inefficient use of one of the most vital categories of health personnel: the public health nurse. This problem has been reported to the subcommittee to exist primarily in relation to tuberculosis project grants and vaccination programs.

The specific practice which the subcommittee questions is the imposition of rigid accounting requirements which necessitate that public health nurses who are paid out of funds derived from a given Federal grant program confine their nursing activities to that program only. This concept of specialized public health nursing is at variance with what the subcommittee believes would be the optimum utilization of these scarce individuals. The experts seemed in general agreement that the public health nurse is one of the most critical people in the supplying of health services. Further, the most economical and suitable means of employing these scarce personnel is in a generalized or comprehensive, rather than specialized, program of family centered nursing activity.

[41] Hearings, p. 254.
[42] See title VI, Public Health Service Act (42 U.S.C. 291-2910).

One of the most valuable witnesses to testify before the subcommittee on this point was Mrs. Margaret B. Dolan, R.N., M.A., professor and head, Department of Public Health Nursing, School of Public Health, at the University of North Carolina. She told the subcommittee:

> The ultimate objective of every service program is to reach and help the individual with health needs. More often than not it is the public health nurse who provides the link between the individual and the service. Yet new programs frequently are planned and established services altered without her knowledge or participation in planning.
>
> The unique contribution of the public health nurse is in her ability to assess total health needs of the families she visits and to provide needed nursing services—bedside care of the ill at home, health counseling and teaching, and assisting the patient and his family to secure needed care and services from other community resources. But the extent to which she can make this unique contribution is determined by the administrative setting in which she functions.
>
> If I could reduce all the problems, concerns, and frustrations I have heard and observed into two concepts I think I would identify them as—
>
> 1. Fragmentation of services.
> 2. Competition for scarce personnel.[43]

This fragmentation and competition referred to by Mrs. Dolan seems to have been brought about by the widespread use of categorical and project grant funding coupled with a high premium on accountability for funds. This frequently has necessitated the assignment of staff on a specialized basis in order to account to appropriate bodies for the categorical funds. Unfortunately, this understandable desire on the part of some HEW subunits to maintain strict accounting procedures has often resulted in a type of program operation at the local level that has produced fragmentation and disruption of nursing services. In the opinion of the subcommittee, implementation and direction of a program should be the prerogative and responsibility of the agency rendering the service.[44] Fragmentation and inefficient use of nursing services arises when the public health nurse is required to confine her activities to a certain category of services (e.g., tuberculosis control). Since the nurse can only be used for one type of activity, it is often then necessary that she be responsible for large geographic areas. This has involved these badly needed women in extensive travel activity; the actual amount of nursing services performed is reduced accordingly.

A less disruptive technique, sometimes resorted to by various State health authorities, is to use the public health nurses in a generalized activity, but require that she keep accurate records of the time which she spends in various activities such as cancer control, heart, tuberculosis, and the like. In one instance reported to the subcommittee a nurse was paid her salary from six different funds, requiring elaborate bookkeeping and time and effort reporting. The present shortages existing in our supply of public health nurses forbids the luxury of involving these badly needed nurses in such extensive traveling and bookkeeping duties. It further seems that suitable accountability for Federal funds could be maintained without insisting on a specialized public health nursing approach. Oftentimes the insistence on this approach seems to have come in the form of interpretative regulations and/or informal guidelines given to the State or local health authorities.

[43] Hearings, pp. 163–164.
[44] See hearings, p. 164.

It is recognized, of course, that certain specialized programs may demand a level of expertise requiring specialized public health nurses. In all other cases, however, the subcommittee recommends that the Department of HEW encourage the generalized, or family centered approach to public health nursing. This recommendation is not made merely as a means of encouraging more efficient utilization of the time of the public health nurses. In addition to the increase in time available for nursing, as opposed to traveling and/or bookkeeping activities, generalized public health nursing brings higher quality medical care to those receiving it. The advantages of the generalized approach to public health nursing were summarized for the subcommittee as follows:

Whatever the source of funds—categorical or project grants—at the local level there must be planning and coordination to insure the most efficient and economical service to people. A unified administration of public health nursing services offering comprehensive service has been found advantageous to the community because—

1. Complete care to individuals and families is more nearly approached than it is through categorically centered services. This approach protects the dignity and privacy of the person needing health service, and recognizes him as an individual who may have a variety of interrelated personal and family health needs. This approach is best implemented at the service level by a public health nurse.
2. Family centered public health nursing permits rendering of service according to patient needs rather than limiting activities to those for which the agency has specialized funding.
3. Family centered service permits the development of a strong nurse-family relationship which enables the nurse to elicit from the family early signs and symptoms which threaten the health of individual family members or the family structure.
4. The nurse's understanding of the family's personal and financial resources make it possible for her to help them to achieve health goals through utilization of the resources available.
5. A family centered nursing service quickly discovers gaps in community resources for meeting health needs.[45]

In summation, sound public health nursing administration is based on the concept of unifying the geographical area and the family approach, rather than fragmenting field work into narrow categories. The family approach avoids confusion for the family, preserves the privacy and integrity of the family, conserves traveltime and expense for the agency, and enhances comprehensive care. The Department of HEW should provide real leadership in doing all that it can to encourage this type of nursing activity. Restrictive regulations on the use of nursing services by State and local health authorities should be kept at a minimum.

RECOMMENDATION H: THERE IS A NEED TO DEVELOP BETTER CRITERIA FOR THE EVALUATION OF PUBLIC HEALTH PROGRAMS

The subcommittee was impressed throughout its study with the fact that no realistic means of evaluating the success of a particular public health or health service program seems to be available. Evaluations presently in use seem to stress activity rather than results. Goals seem to be defined not in output terms of reduction of public problems, but primarily in input terms of services to be provided. This would seem to put a premium on activity rather than accomplish-

[45] Id., p. 165.

ment.[46] This tendency was outlined, insofar as it pertains to mental health, by Dr. David J. Vail, director of medical services, Minnesota Department of Public Welfare, who testified before the subcommittee:

> I think we are aiming more in the area that we call input; that is, the way to deal with this is to obtain certain professional staff, establish a mental health center, etc., etc., so that this becomes, then really the end of the whole operation, that if you have your mental health center, you have done what you were supposed to do.
>
> But this is not true, the truth is that you cannot get to where you are going until you have defined the goal, and have charted some course of getting there.[47]

Dr. George James, dean of the Mount Sinai Medical School, and Chairman of the Task Force on Community Assessment, Planning, and Action of the National Commission on Community Health Services, expressed the same thought before the subcommittee:

> I think that it is very important to measure accomplishment. I do not consider that this is any abridgement of freedom on the part of a State or local agency * * *
>
> This means that the Public Health Service would have to have very excellent teams of well-trained medical and other skilled personnel, who would be responsible for studying need, seeing the State plan, going over the State plan, and also following up the results to see what has been the accomplishment, and if it is found that the State has major problems and is not allocating funds to the control of these problems, then it is fair for the Public Health Service to ask why this is so. * * *
>
> Now this is a two-way affair. The State and other agencies within it will have an opportunity to talk back, but there should be more concern over the way this money is spent, and the allocation should not be by some simple fiscal formula.[48]

It would seem to the subcommittee that the fullest progress in the design and implementation of health programs cannot be obtained without taking the essential step of developing meaningful and valid yardsticks by which to measure the utility of the programs in question. Goals must be established, and particular targets spelled out in order to provide a way of measuring the effectiveness of various health programs. "We must measure our effectiveness by performance and change in family behavior rather than by numbers of staff employed, moneys expended or new services created."[49] In short, a proper accounting for the expenditure of public funds would seem to require the development of goals which are more meaningful than those which have been used heretofore. This, in itself, will require considerable planning and research. The goals must be selected and defined in such a manner that they be measured in as objective terms as possible, rather than in subjective terms.[50] Furthermore, the information which will be needed to assess the effectiveness of a program should be determined in advance, so that procedures for collecting and recording such information can be incorporated into the planning of the program. Only thus can there be any assurance that the information necessary for subsequent evaluation of the program's accomplishments will be available when needed.

[46] Hearings, p. 58.
[47] Id., p. 70.
[48] Id., pp. 90–91.
[49] Id., p. 165.
[50] Id., pp. 341–342.

RECOMMENDATION I: THERE IS A NEED FOR INCREASED RESEARCH ON METHODS OF DELIVERING HEALTH SERVICES

The Federal effort in support of basic biomedical research is intensive; however, it must be noted that such research, of itself, can do nothing to improve the Nation's health. Other necessary steps still remain to be taken, including research as to the most efficient methods of organizing health services, and delivering to the people the applications of basic research. In the opinion of the subcommittee, there is need for greater emphasis in sponsoring research of this latter type. The need for greater effort in this direction has been noted elsewhere. It was reported at last year's White House Conference on Health that:

> We spend less on health research than we should. But of our health research expenditures, less than one-half of 1 percent is spent for research on the organization and delivery of health services.[51]

While not wishing to minimize the importance of basic biomedical research to the advancement of the Nation's health, the subcommittee must also note that the substantial investment of public funds in supporting this basic research must be protected by energetic and imaginative efforts to bring the fruits of the knowledge thus obtained into widespread application. This point was strongly emphasized in a recent report to a sister committee, prepared by a group of health experts:

> Forces both within and outside the health field have combined to produce a gap between the volume of scientific knowledge available to the health professions and the community, and the amount of that knowledge actually being used to save lives, prevent disability, and restore human productivity. The cost paid by the Nation for this imbalance is staggering in both humanitarian and economic terms. A major national effort is required, first to bridge the gap and eventually to eliminate it * * *. The fundamental elements upon which comprehensive services depend are improved knowledge and methods, manpower, facilities, organization of more effective services, and financing.
>
> Scientific research can be carried out in relation to each of these fundamental elements. Indeed, the national effort to deliver the best in modern health services can succeed only if scientific methodology, which has been so brilliantly successful in developing biological and medical knowledge, is employed imaginatively to the solution of problems related to the institutions and individuals which provide and receive health services.[52]

The importance of this research was echoed in the report of the President's Commission on Heart Disease, Cancer, and Stroke:

> Such research is of singular importance to the health establishment if we hope to achieve new methods of patient care, and more adequate approaches for the delivery of high-quality health services that incorporate the very latest biomedical achievements. * * * Research in health services can enable us to achieve the maximum yield in both quantitative and qualitative terms from our existing health manpower.[53]

The report went further and discussed the importance of a sequence of efforts from new discoveries to widespread implementation that exists in other sectors of our national life and must be sought in health:

> The next logical step following the acquisition of new knowledge to implement these findings (is) through demonstration projects. In areas other than health, development is recognized as the companion of research. Such a relationship

[51] Hearings, p. 101.
[52] A Report to the Subcommittee on the Departments of Labor and Health, Education, and Welfare and Related Agencies of the Committee on Appropriations, U.S. House of Representatives (July 1964).
[53] A national program to conquer heart disease, cancer, and stroke. Report to the President, vol. II (1965), p. 285.

and its merits are often overlooked in the health establishment. The principle of coordination of health services or of comprehensive care that are formulated through research must be tested and improved through repeated attempts at implementation in different settings. The health establishment can profit from the extraordinary achievements in industry where basic research, applied research and development are carried out sequentially in pursuing an objective.[54]

It would seem that research of this type should receive a high priority by the Department of HEW if the nation is to receive the ful benefit of its investment in basic biomedical research.

In order to launch a research and demonstration program in the organization and delivery of health services that is commensurate with the challenge, the Public Health Service must draw on the competence and expertise of a diverse group of knowledgeable people.

Several of the witnesses appearing before the subcommitteee or corresponding with it indicated that such advice and guidance are not now being utilized sufficiently. Some commented on the makeup of the reviewing study sections as an illustration of the lack of essential breadth and diversity of advice. Dr. Charles L. Wilbar, Jr., Pennsylvania secretary of health, for example, told the subcommittee:

> The National Institutes of Health have such a large number of requests for grants that they must have many reviewing committees consisting of persons who are not employees of the Public Health Service, but serve on a part-time basis. Most of these reviewing committees are made up of university oriented and clinical or basic science oriented persons. Consequently nonuniversity organizations, such as hospitals or health departments, do not seem to receive the attention, as far as research grants are concerned, as they might from a group of reviewers who are not primarily university oriented.
>
> Also, it seems to us that badly needed applied and methodology type of research has received little backing from the National Institutes of Health. This research concerned with methods of obtaining popular application of the findings of clinical and basic scientific research is extremely necessary to help bridge the gap between scientific knowledge and its widespread use.[55]

The same thought was expressed by Dr. John H. Venable, director of the Georgia Department of Health:

> May I say just a word also about the makeup of the study committees and sections which review project grant applications. These have been predominantly made up of university or academic persons with, I think, entirely too little representation from the service agencies. Many decisions have been made that I think perhaps would have been modified had there been people from the firing line adequately represented in the advice that has led to these decisions.[56]

The subcommittee was heartened recently by the announcement of Surg. Gen. William H. Stewart to the effect that Government health research funds in the future will lay heavier stress on medical projects that promise specific clinical applications.[57] It is hoped that research on public health organization, methods, and techniques of delivery will receive increased emphasis by the Department.

RECOMMENDATION J: THERE SHOULD BE INCREASED EMPHASIS OF COMPREHENSIVE SUPPORT FOR HEALTH SERVICES, WITH A CONCURRENT DEEMPHASIS ON CATEGORICAL GRANTS AS INSTRUMENTS TO SUPPORT HEALTH SERVICES

In lending its support to the proposed legislation H.R. 13197, and its companion bill in the Senate S. 3008, the Department has already

[54] Id., pp. 285–286.
[55] Hearings, p. 133.
[56] Id., p. 25.
[57] See Medical Tribune; vol. 7, No. 71 (June 13, 1966), p. 1.

taken significant action in effectuating the recommendation which the subcommittee now makes. The subcommittee found almost unanimous agreement on the part of health experts from all levels of government, and from the academic world, on the principle that the categorical and the project type of grant programs as means of supporting health services are in need of serious reevaluation. This recommendation is by no means new or original with this subcommittee.

Previous suggestions for improvement, with respect to categorical funds, have centered around the concept of allowing to the States discretion in reassigning funds from one category to another up to a fixed percentage. The following findings and recommendations, for example, are found in the report of the Advisory Commission on Intergovernmental Relations, dated January 1961:[58]

> The Commission believes it to be evident that although the original purpose of the various categorical grants in the field of public health were to stimulate increased State and local activity in the particular categorical field, the Congress has long since by its action in continuing and increasing the sums available, demonstrated an intent that these grants also serve as a permanent contribution by the National Government to the support of the respective State and local activities. The States by their actions in providing funds for these categories considerably in excess of matching requirements, have shown that they visualize the provision of health services in general, and in each of the categories to be a continuing responsibility of State government.
>
> It is recognized that within each specific category the use of project or demonstration grants may serve a stimulating purpose with respect to new approaches and techniques which may be employed to advantage in coping with a particular public health program. In general terms, however, the States no longer need stimulation to establish and carry on the categorical program of the scope envisaged by the grants. Although here and there individual States may not be providing ample funds for all of the categories, it would seem that an adequate time period has been provided (15 years as a minimum) for stimulative purposes (report, pp. 16–17).

The 5 years which have intervened since the publication of the Commission's report have only emphasized the correctness of its conclusions on this point. In the subcommittee's view, the project and categorical funds, insofar as they are applied to existing health services programs, have substantially served their original purpose of stimulation. They appear to be unsuitable for the primary needs of the present time; i.e., the need for a firm base of coordinated Federal support to States and communities for the provision of comprehensive health care and health services. One of the most serious drawbacks of the present project/categorical approach has already been discussed above with respect to its detrimental effect on the administration of public health nursing activities (see recommendation G, p. 40 of this report.) Many witnesses and correspondents contacting the subcommittee expressed the hope that some way could be found whereby project and categorical-type funding could be restricted to special projects or research, where it is more appropriate, and that a more general form of financial support be made available for the purpose of assisting basic health programs. A county health officer, for example, testified as follows concerning project grants:

> We would hope that the project-type funds, the short-term things, would be reserved for research or special study. We don't see this mechanism as offering a thing when it comes to regular funding of basic programs. We think projects

[58] "Modification of Federal Grants-in-Aid for Public Health Services," Advisory Committee on Intergovernmental Relations (January 1961).

should be reserved for the things that need clarification, need exploration. They shouldn't be used at large just as another device for contributing money.[59]

The subcommittee was particularly impressed with the testimony of Mrs. Margaret B. Dolan, R.N., M.A., professor and head of the Department of Public Health Nursing, School of Public Health, University of North Carolina. She stated that the two basic detriments to more effective provision of health care are (1) fragmentation of services, and (2) competition for scarce personnel. Concerning these serious detriments she stated:

> I believe two mechanisms that have been increasingly used in financing health programs and activities have been responsible to a large degree for creating these two problems—fragmentation and competition for scarce personnel. They are the use of categorical funding and project grant funding.[60]

One of the principal drawbacks of these types of funding seem to be concurrent requirements for specialized staffing at the local level. This has accounted for many instances of poor administrative practice which have been related to the subcommittee. The project mechanism, moreover, has seemed to lend itself qute well to the development of the type of direct Federal-local arrangements which are detrimental to the ability of State health departments to participate in the overall planning process. The result may be a lack of coordination among various areas within a given State.[61]

Perhaps one of the most telling arguments against the use of the project-categorical funding approach to the provision of basic health services is contained in the following statement made by Dr. George James, dean of the Mount Sinai Medical School and chairman of the Task Force on Community Assessment, Planning, and Action of the National Commission on Community Health Services. Dr. James testified before the subcommittee on April 19, 1966:

> It is important to emphasize one major overriding principle: the pace of scientific and social change in this era is so rapid that every health program must be considered as experimental and tentative in both its scientific and organizational components. This suggests strongly that legislation must permit a maximum of flexibility consistent with its overall purpose. It implies that rather than insisting upon uniformity of approach, legislation and Federal organization should emphasize experimentation and innovation.[62]

It is somewhat paradoxical that the categorical and the project granting methods, whose original purpose was innovation, may now have become a principal roadblock to innovation in the provision of health services. One of the principal reasons for this may be the zeal with which the administrators of the various programs have sought to insure that the funds dispersed under their jurisdiction are in no way allowed to be used in other activities. This has resulted in many restrictive regulations, both formal and informal, which have interfered with sound administration and with logical use of the scarce health resources, especially manpower, available at the State and local levels. It seems inevitable that the more detailed the legislation and the regulations attached to a program, the greater the likelihood that it will not fit a number of States.

[59] Testimony of Henrik Blum, M.D., county health officer, Contra Costa County, Calif. Hearings, p. 117.
[60] Hearings, p. 164.
[61] Id., pp. 183–184.
[62] Id., pp. 81–82.

An example of this type of difficulty was presented to the subcommittee by Governor Chafee of Rhode Island:

* * * My own State receives more than three times as much money for heart disease control than it receives for cancer control. Yet, at the moment, conditions are ideal for more effective programing in cancer control activities than they are in heart disease control activities because of community interest and professional capabilities. This does not mean that heart disease money is not used wisely, but if heart disease control funds, cancer control funds, and chronic disease funds were combined, my department of health would have much more latitude in programing, and it would be more beneficial to the citizens of our State. It would result in meeting true local needs rather than theoretical Federal needs.[63]

It is primarily because of such considerations that the subcommittee feels that Federal funds destined to underwrite the provision of basic health care and services at the State and local level should be provided with only such accounting restrictions as are consistent with appropriate accountability for the expenditure of public funds.[64]
On this point the subcommittee is not convinced that the imposition of rigid regulations and categorical boundaries is the best method by which to insure that Federal funds are not wasted. Actually, the opposite may well be true:

Money that is available only for a narrower specific purpose is often money that the administrator has no incentive to avoid wasting because he cannot apply any savings to any other program. If he saves it, it is nevertheless lost to him. Saving just to be able to return the money loses much of its incentive.[65]

If progress can be made toward the objective of having funds available for much broader purposes, the administrator should have a greater incentive for saving, or in any event not wasting, money. Such funds would then be available for other program needs, and the administrator would have the satisfaction of seeing his available resources accomplishing much more than had been anticipated.

It is not the purpose of this recommendation to suggest that categorical and project funding has no further role to play in the Federal support of health services. Special efforts, and specialized grant programs, may still be needed to deal with special health problems. But even such specialized problems will still need the basic support of good local and State health departments. By limiting the categorical and project approaches to such specialized needs, however, many of the present distortions of over and under emphasis would be avoided.[66] Moreover, the compartmentalized and piecemeal variety of planning would be, to a large extent, eliminated. The States would be given the freedom of action necessary to provide for the best possible health care of their citizens. During the course of its study, the subcommittee received many opinions similar to the one given by Dr. Wilson T. Sowder, head of the Florida State Board of Health, who told the subcommittee:

As a matter of fact, it is most difficult for States to actually do any real planning of their own at all for programs of the project type. I say this in spite of the volumes of documents forwarded to Washington each month bearing the names of plans for projects. Such planning is actually in most cases being done at the Federal level and handed down to the States in the form of guidelines, liberally supplemented by oral and written suggestions as to the type of project that wil

[63] Hearings, pp. 5-6.
[64] Id., p. 254.
[65] See statement of Dr. Alfred L. Frechette, commissioner, Massachusetts Department of Public Health; hearings, p. 282.
[66] One such distortion, the establishment and support of a glaucoma screening program in a community which as yet had no health department, was described to the subcommittee. See hearings, pp. 282–283.

be entertained. This situation is not fair to the States and the local health departments, and discourages the development of real State and local plans based on their needs.[67]

In short, the experts with whom the subcommittee has been in contact, including those from within the Department, seem to agree that with respect to the existing health services programs the need for Federal "stimulation" is past, and that what is needed now is a continuing support for comprehensive general health programs. A basic objection may perhaps be anticipated to a recommendation that project and categorical grants be deemphasized. It may be paraphrased: The Federal Government cannot give a blank check to the States. As to this, the subcommittee is in entire agreement. Nevertheless, the recommendation that the subcommittee now makes in no sense constitutes the providing of a "blank check." The subcommittee believes that appropriate accountability for Federal tax funds will be maintained by a requirement that the State submit a comprehensive plan acceptable to the Federal authorities. Pending legislation H.R. 13197 contains such a provision. While the Federal Government should require that such a plan be comprehensive and logical, stifling restrictions circumscribing the judgment and initiative of the State and local health authorities should not be imposed. The increasing sophistication of the American public in matters of health will encourage efficiency and sound management of health services by authorities at the State and local level. In addition, further safeguards could be imposed through the use of program audits by the HEW Audit Agency (see recommendation L below).

RECOMMENDATION K: COMPETITION BETWEEN HEALTH AND WELFARE AGENCIES SHOULD BE TERMINATED

While competition is an essential force in our Nation's economy, it is not an unmitigated benefit when applied to the field of health services. The subcommittee can see little excuse for two separate arms of government, State or Federal, seeking to provide the same services to the same recipients or "clients." Nevertheless, such a situation does exist at the present time. Perhaps the final solution to the problem must await the establishment of a Federal Department of Health and initiation of comprehensive health planning at the Federal level as recommended above. One of the elements of such planning would be the delineation of areas of health responsibility and activity for the different agencies of government. It is the lack of any clear-cut understanding as to these areas which, in large part accounts for the present unfortunate situation. Nevertheless, by the exercise of its position of leadership in the health affairs of the Nation, the Department of HEW could do much to alleviate some of the present difficulties. The Secretary of HEW has been given very broad authority in this regard, particularly since Reorganization Plan No. 3 of 1966 became effective, and it is to be hoped that he will not be timid and no longer hesitate to intervene actively and firmly to eliminate competitive activities and attitudes between health and welfare agencies.

Competition between health and welfare agencies, each of them attempting to supply health services to the same segment, or overlapping segments, of the population results in confusion and waste

[67] Hearings, p. 289.

of scarce health manpower. Such competition is presently going on, both at the State and at the Federal level.

The recently enacted Social Security Amendments of 1965 provided, in title XIX thereof, a specific provocation for competition between health and welfare agencies. Title XIX provides for Federal aid to the States to provide medical care for needy persons. Under this title, States receiving Federal aid must designate a single State agency to administer this program, which expands and consolidates various health programs under five older titles of the Social Security Act. Medical assistance grants to the States under title XIX are administered by the Welfare Administration, Department of HEW, on behalf of the Federal Government.

Title XIX, as enacted by Congress, left to the Governor of each State the option of selecting the agency within his State government which would administer the title. There is much evidence that a good deal of unseemly competition has already taken place with various State health and welfare agencies acting as rivals seeking to secure the authority for administering the health care services to be provided under the title XIX program. In this a distinction must be drawn between the determination of eligible recipients of health care under title XIX, certainly a proper activity for welfare departments, and the actual administration of the delivery of health care. This latter function, which cannot be satisfactorily performed without substantial medical staff and expertise in public health methods, should remain in the State agency best able to meet these requirements. Normally, this agency would be the State health department.

It is not necessary, however, that the State health department be designated by the State Governor as the single State agency to administer title XIX. The State department of welfare, or another State agency can be designated as the single State agency to administer title XIX within that State so long as eligibility is determined by the welfare agency. In such alternative situations, duplication and fragmentation of health services and medical personnel can be avoided by arrangements for the actual provision of medical care by or through the State department of health under suitable contractual relationships.[68] While this seems a very satisfactory method of conserving medical personnel and facilities, and insuring coordination of all health services within a State, there is disturbing evidence that competition and rivalry between health departments and welfare departments, at both State and Federal levels, is interfering with the setting up of such contractual relationships.[69] The problem and the results thereof are indicated in the following exerpts from the testimony of Dr. Bucove:

> Mr. Sloat. Dr. Bucove, going back to this question of the title 19 problem, we have been told that possibly the most serious problem facing the State health departments at this time is the question of what is going to happen to them if the State welfare departments are designated as the title 19 administrative agencies. We have been told that the welfare departments, when so designated, will probably develop very sizable health and medical operations, and in effect, take over the health activities of the State.

[68] See testimony of Hon. Wilbur J. Cohen, Under Secretary of Health, Education, and Welfare. Hearings, pp. 318-319.

[69] See hearings, pp. 150-151; 154; 186-187; 190; 233-243; 246; 311; 325-327; and 330-332.

Will this not lead, in your opinion, to competition between the welfare and the State health departments for scarce health manpower and wasteful duplications of health money?

Dr. BUCOVE. There is no question about this at all—and I believe I indicated considerable concern for this kind of thing happening.

As I cited, this is already occurring in a number of States, and even in my own State, where we have had excellent working relationships with our welfare department. [In] the plan which they submitted to the Federal welfare agency, they have indicated that they plan to get into such things as preschool health examinations, immunization programs, and this kind of thing, and we have been pressing our welfare departments to assist us in this for years, and now there seems to be a suggestion that they may attempt to do this themselves, and I think this would be obviously, to me at least, the wrong thing to do. They ought to reinforce what we are doing, through perhaps a contract agreement, rather than setting out on their own.

Mr. SLOAT. I believe you heard Dean Wegman [70] earlier this morning suggest that a very simple solution to this serious problem would be to have the welfare department contract out the health services to the health department.

As things now stand is there any incentive for the welfare department to do that, or are they likely to want to build up their own health activities and enlarge their own domain, particularly, if, as I understand it, they are being encouraged by the Federal agency to do so?

Dr. BUCOVE. The incentive, it would seem to me, would be in developing for the State a coordinated program. Now this to me would be the incentive, but it is my understanding that the State welfare agencies are indeed being discouraged to do this by the Federal agency.

Mr. GILLIGAN. Did I understand you to say a moment ago that you felt that the Federal Government was at the present time, at least in practice if not in theory, discouraging the cooperation between the agencies?

Dr. BUCOVE. Yes, sir.

Mr. SLOAT. Is this the Welfare Administration that is encouraging, so to speak, the welfare agencies in the States to keep title 19 health activities within their own domain?

Dr. BUCOVE. Well, the answer has to be yes, as I understand it.[71]

A number of other sources reported to the subcommittee instances wherein representatives of the HEW Welfare Administration sought to influence State governments to place the administration of title XIX within their welfare agencies. These representatives have also sought to discourage contractual arrangements whereby a State health department would administer the medical care provisions of title XIX in States where the welfare agency is designated as the single State agency for overall administration of the title.[72] It appears that this competitive spirit is not attributable to the official policies of the leadership of the Welfare Administration or the Public Health Service. Rather, it seems to stem from the activities and decisions of overzealous subordinate personnel.

Much of the difficulty seems to have arisen due to the wording of section 1903(a)(2) of title XIX. This section stipulates the percentage of Federal matching funds which is to be awarded to States for medical activities under the title. It reads, in pertinent part:

> [A]n amount equal to 75 per centum of so much of the sums expended * * * as are attributable to compensation or training of skilled professional medical personnel, and staff directly supporting such personnel, of the State agency * * *.

Elsewhere in the section, a level of 50 percent is stipulated for Federal matching funds in connection with all other amounts expended by the State agency administering the title. This has been interpreted as meaning that medical activities carried out under contractual arrange-

[70] Dr. Myron Wegman, dean, School of Public Health, University of Michigan. Statement on p. 149 of hearings.

[71] Hearings, pp. 189–190.

[72] See note 69, supra.

ments with a State health department, where the State welfare agency has responsibility for overall administration of title XIX, can only be reimbursed at a level of 50 percent by the Federal Government. This has been held to follow from the wording of the section to the effect that the 75-percent level of Federal participation attaches only to sums expended for compensation or training of professional personnel, and supporting staff, "of the State agency." Under an arrangement whereby the State welfare agency is designated as the State agency to administer title XIX, medical personnel of the State's health department, even if under contract to the State welfare department, could not be considered personnel of the State agency administering the title. Their compensation, therefore, would only be subject to a 50-percent level of Federal reimbursement.

The effect of this interpretation is to encourage the establishment of a separate medical capability in the State agency administering title XIX. Where this State agency is not the State health department, duplication and waste of medical resources seem inevitable. The subcommittee therefore recommends that the Congress make any necessary changes in the wording of section 1903(a)(2) to allow for the same proportion of Federal matching funds to support the medical care activities of title XIX, regardless of where the medical responsibility is placed.[73]

If the Nation's health effort is to succeed, we need the fullest measure of cooperation among all levels of government. There is a clear need, in the subcommittee's view, for a greater dialog in this area. The subcommittee was greatly heartened by the statement of the Honorable Wilbur J. Cohen, Under Secretary of Health, Education, and Welfare during the subcommittee's hearings.

> I believe that we are in a great transitional period right this minute. For 30 years in this country there has existed a tremendous ideological conflict about medical economics, the role of the Federal Government in medical care and particularly with regard to insurance and medical assistance * * *. We are now in an era of cooperation. We are now in an era of good relationships, working relationships between the medical profession and the nonmedical groups, the insurance people and others, medical relationships between assistance and nonassistance people, between the public health people and others, between the Federal agencies and State agencies. I see that we are now at a point where we can go forward to make progress which it was never possible to do before 1965 simply because you had this overlay or undercurrent of controversy and debate and mixed feelings about what the proper role is.[74]

While the thoughts expressed by the Under Secretary are indeed encouraging, the subcommittee cannot help but feel that the "ideological conflict" has not as yet died out between health and welfare agencies. It is the hope of the subcommittee that we really are coming into an era of improved cooperation and better working relationships in national health matters. Such improvements will necessitate improved understanding by all levels of government of the viewpoints and problems of the others. There is need for such understanding at all levels of government if the expectations of the American people are to be fulfilled.

[73] See testimony of Hon. Wilbur J. Cohen, Under Secretary of HEW; hearings, p. 320. See also, statement of Dr. Lester Breslow, director, California State Department of Public Health; hearings, p. 241.
[74] Hearings, p. 323.

RECOMMENDATION L: THE HEW AUDIT AGENCY SHOULD PLACE INCREASED EMPHASIS ON "PROGRAM" AUDITS TO ASSURE EVALUATION OF STATE AND LOCAL HEALTH PROGRAM ACCOMPLISHMENTS, RATHER THAN MERELY "FISCAL" AUDITS

An essential requirement for assuring the success of any program is an effective followup procedure to evaluate the accomplishments of the program in terms of its stated objectives. Such a requirement is particularly necessary and appropriate where the expenditure of public funds is involved.

One of the most useful techniques for evaluating a program is through the utilization of a program audit to determine what specific accomplishments have been achieved as a result of the money expended. In order to ascertain the extent and effectiveness of the Department's audit activities the subcommittee undertook an examination of the Department's audit procedures for the formula grants and health services project grants (as distinguished from research project grants and training grants) administered by the Bureau of State Services of the Public Health Service.

Although the Department's audit activities in the past have been seriously deficient in a number of respects, the Department currently is instituting a number of changes to improve them. Despite the corrective measures being undertaken by the HEW Audit Agency, it is apparent that increased emphasis needs to be placed by the Audit Agency on program-type audits to assure evaluation of State and local health program accomplishments rather than merely on fiscal audits of the type made chiefly by the Department in the past.

A brief summary of the review and audit procedures for health services formula and project grants administered by the Bureau of State Services and of the subcommittee's recommendations in regard to the HEW audit procedures follows:

Review and audit of health services formula grants

There currently are nine formula grant programs administered by the PHS, under which funds are made available annually to States in accordance with formulas prescribed by law. The formulas are based on (1) State populations, (2) the extent of the particular health problem, and (3) the financial need of the respective States.[75] The method of allotment of funds under these formulas is set forth in regulations issued by the Public Health Service.[76]

The following table shows the nine categories of formula grants, the legal basis for each, the primary PHS review division and the fiscal 1966 appropriation for each grant.[77]

[75] PHS Act, sec. 314.
[76] 42 CFR, pt. 51.
[77] See also app. D, chart 4.

PHS formula grants

Formula grants	Legal basis	PHS review division	Appropriation, fiscal year 1966
Cancer control	Annual appropriations acts.	Division of Chronic Diseases	$3,500,000
Chronic illness and aged.	Sec. 314(c), PHS Act	do	12,300,000
Dental health	Sec. 314(c), PHS Act	Division of Dental Public Health and Resources.	1,000,000
General health	Sec. 314(c), PHS Act	Division of Community Health Services	10,000,000
Heart disease control	Sec. 314(c), PHS Act	Division of Chronic Diseases	9,500,000
Home health services	Sec. 314(c), PHS Act	Division of Nursing	9,000,000
Mental health	Sec. 314(c), PHS Act	National Institute of Mental Health (NIH).	6,750,000
Radiological health	Sec. 314(c), PHS Act	Division of Radiological Health (EH)	2,500,000
Tuberculosis control	Sec. 314(b), PHS Act	Communicable Disease Center	3,000,000
Total			57,550,000

The Office of Grants Management, in the Bureau of State Services (Community Health), develops regulations and procedures governing the administration of formula grants and participates in grant administration with the Department's regional offices. The Mental Health and Radiological Health formula grants are administered by the Office of Grants Management to the extent that they are included in State or community plans. However, the professional review of these two grants is the responsibility of the National Institute of Mental Health and the Division of Radiological Health (BSS-Environmental Health), respectively.

Formula grants are made on the basis of plans which are submitted by the States and communities to the HEW regional offices. PHS employees in the regional offices assist the States and communities in the preparation of the State plans, and upon their completion review them. These reviews are made by professional staff members, trained in medicine, dentistry, psychology, public health, and nursing, and are intended to provide an evaluation of the health programs of the States and communities with a view to seeing that Federal funds will be expended in accordance with the aims of the Congress and the PHS.

After the plans have been approved by the regional offices, they are sent to the appropriate divisions in the Bureau of State Services [78] in Washington (see table this page) for further review by their professional staffs to assure that they are sufficiently comprehensive to justify the grants. After such final approval, and appropriation of funds by the Congress, allotments are made on the basis of the established formulas.

The Department makes post audits, on a random sample basis, of disbursements made by the States under the formula grant programs. The HEW audit staffs are located in each of the nine HEW regional offices. It has been the general practice of the regional audit staffs to assign a number of auditors on a permanent basis to most of the State capitals where most of the State records are kept. Despite this practice, however, HEW audits of funds expended by the States under the formula grant programs have sometimes fallen so far in arrears, in some HEW regions, as to vitiate to a large degree any benefit that could be derived from the audits.

[78] Review of formula grants for mental health, however, is performed by the National Institute of Mental Health.

In addition, HEW audits have emphasized the adequacy of financial accounting of grantees rather than attempting to evaluate the accomplishments of the State and community programs. Most of the efforts of the auditors have been directed to the examination of disbursement documents to determine the legality of the disbursement and the accuracy of the accounting treatment and to see that Federal grant funds were matched by State or community funds as required by law (usually on a dollar for dollar basis) for the various health categories included in the plans. In general, however, evaluations were not made to see whether the plans accomplished their purposes or whether PHS professional staff members had made reviews to see that the plans were effective.

Review and audit of health services project grants

Project grants are grants made for specific purposes for specific periods. These grants are made in the following 11 health categories for studies, demonstrations, etc., and to meet types of health problems which are not directly related to the size of State populations:

Health services project grants administered by the Bureau of State Services

Health category	Division	Advisory committee	Appropriations, fiscal year 1966
	COMMUNITY HEALTH		
Cancer	Division of Chronic Disease	Cancer Control Program Advisory Committee.	$13,933,000
Neurological and sensory diseases.	do	Neurological and Sensory Disease Service Advisory Committee.	2,750,000
Mental retardation	do	Mental Retardation Grant Review Committee.	7,250,000
Community health services	Division of Community Health Services.	National Advisory Committee on Public Training.	10,000,000
Migrant workers family health clinics.	do	Migrant Health Project Review.	3,000,000
Tuberculosis control [1]	Communicable Disease Center.	Tuberculosis Control Advisory.	9,700,000
Immunization (vaccination assistance).[1]	do	Immunization Practice Advisory Committee.	8,000,000
Venereal disease control [1]	do	Venereal Disease Control Advisory Committee.	6,229,000
Subtotal			60,862,000
	ENVIRONMENTAL HEALTH		
Control program [1]	Division of Air Pollution	Air Pollution Program Grants Advisory Committee.	5,000,000
Survey and demonstration [1]	do	do	1,850,000
Demonstration and investigation.	Office of Solid Wastes	Office of Solid Wastes Review Committee.[2]	2,000,000
Subtotal			8,850,000
Total			69,712,000

[1] Grants in these areas normally are reviewed only by professional staff members of the divisions, under policies and principles established by the advisory committees. The staffs request guidance and advice from the advisory committees when deemed necessary.

[2] This committee is composed of professional staff members of the division rather than of outside consultants appointed by the Surgeon General.

Applications for health services project grants are submitted to the appropriate BSS divisions. Administrative assistance is furnished by the Office of Grants Management for grants submitted to the Com-

munity Health Divisions and by the Office of Resources Development for those submitted to the Environmental Health Divisions.[79]

Those who may receive project grants include States, State-designated agencies such as health departments, local public agencies, nonprofit private agencies or institutions, universities, medical schools, research institutions, and hospitals.

Applications are reviewed initially by professional staff members of these divisions, sitting as ad hoc committees, and are rated by them for scientific merit. The applications are rated numerically from one to five, one being the highest. Applications are then referred to an advisory committee of outside consultants.[80] These advisory committees are authorized or established by the legislation which authorizes the various grant programs, and the members are appointed by the Surgeon General. They consist of persons from specialized fields who serve on a consultant basis, and they meet several times a year in Washington. The advisory committee review is done largely on a block basis; that is, only those grants having low ratings or involving larger dollar amounts are reviewed in detail. Final approval of the grant application rests with the head of the applicable division as the designee of the Surgeon General.

The HEW regional auditors make periodic reviews of the projects at the sites of the projects. These audits also are made on a selective basis only. The subcommittee is informed, however, that the auditors attempt to audit all the larger grants. Much of such audit work is done at the same time that the State formula grant audits are being made, because some formula and project grants are being carried out at the same sites, such as health departments, hospitals, and the medical departments of universities.

As in the case of formula grants, audits of project grants have been largely of a fiscal nature in past years. In general, evaluations were not made to see whether the projects accomplished their purposes or whether PHS professional staff members had made post reviews to see whether the projects were effective.

Reorganization of the HEW audit activities

A comprehensive review of the Department's audit policies and practices was made by an independent advisory panel to the Secretary of HEW, and the panel's report was issued in July 1964. As a result of this report, entitled "Evaluation of DHEW Audit Activities," the Department has instituted a number of significant changes in its internal audit organization.

The most critical weakness pointed out by the report was the multiplicity of audit organizations. There were 15 officially recognized audit organizations scattered throughout the various HEW agencies in the Washington, D.C. area, in addition to the grant-in-aid audit organizations located in the nine HEW regional offices. This proliferation resulted in an almost complete lack of definition of audit objectives and audit policy.

The report also stated that the level of competence of the several audit organizations varied greatly. A few staffs were competent.

[79] Research, training, and fellowship grants funded by the various divisions of BSS are sent to the Division of Research Grants at NIH and are reviewed initially by one of the 76 study sections under the DRG and then by the appropriate program advisory committee to the various divisions of BSS, following the same procedures for such grants funded by the various institutes and divisions of NIH.

[80] See table p. 55, n. 1., however.

Others were found wanting in many respects, particularly in that their efforts were limited to auditing the fiscal aspects of the programs of the grantees; that is, most of their time was devoted merely to an examination of disbursement documents to determine the legality of the disbursements and the accuracy of the accounting treatment. It is generally recognized that fiscal audits are not very useful to those making management decisions. Decisionmaking and resource control should be audited at all levels to assure that adequate policies and controls exist and that they are functioning. Effective audit requires that the State plans be evaluated for effectiveness in achieving their intended purposes. For example, auditors could check to see that complete and proper case files are being maintained for patients and recipients of aid and that professional staff members review case files, records, and reports of a clinic to see that they are properly maintained so that PHS professional staffs will have a sound basis on which to evaluate the efficiency and effectiveness of clinic activities.

The panel also stated that there was a serious lack of an adequate staff recruiting and staff development program which is essential for the continuing efficient functioning of the audit activity.

As a result of the study, the panel recommended (1) that the number of audit organizations be substantially reduced, (2) that the chief auditor report to an Assistant Secretary of the Department, (3) that the level of competence of the staffs be improved, and (4) that a cohesive plan for recruiting and staff management be developed and implemented.

The Department has hired a Director of a newly created Audit Agency and combined most of the audit organizations, including all of the regional staffs, into a single organization. Only two audit staffs remain separate, one auditing the Washington headquarters office of the Public Health Service and the other auditing the Baltimore headquarters office of the Social Security Administration. However, the Director of the Audit Agency has authority to set audit policies for the two separate groups and to direct their efforts to areas he deems appropriate.

In addition, during the past year a substantial number of additional auditors have been employed, most of whom have been assigned to the HEW regional offices.

The HEW Audit Agency on June 15, 1966, issued instructions, entitled "Interim Audit Instruction C–6, State and Local Audits, Public Health Service Formula Grants," to all regional office staffs and to Washington office personnel to change the audit emphasis for formula grants from a fiscal approach to an evaluation of the activities of the grantees.

Under the new instructions, the regional auditors are now required to see that reviews of operations under the formula grant programs are made by PHS regional representatives and that technical and administrative guidance is furnished the grantee by PHS. The new audit instructions also require that an evaluation be made as to whether each program being financed has been expanded to the extent that Federal funds have been granted rather than having Federal funds substitute for what the States would otherwise have spent without aid. (It has been the policy of the Office of Grants Management to require the States to meet this requirement in all formula grant programs despite the fact that authority for such a requirement

exists only in the category of chronic illness and related health problems of the aged.)

It appears that the HEW Audit Agency now is also attempting to develop a "program"-type audit in order to evaluate the efficiency and effectiveness of health services project grants. New audit instructions (thus far communicated only informally, however) call for audits to be made for the purpose of (1) seeing that the proper professional staffs in the agency's regional offices have made the necessary evaluations of the applications and plans and the evaluations of the progress of the projects, and (2) examining vouchers, records, and other documents to see that Federal funds have been properly expended on the projects in accordance with the terms of the plans. Also, the new audit instructions require a review of the internal audit activities of the grantees and reports on any deficiencies noted. The subcommittee is informed that these requirements will be set forth in new written audit instructions now in preparation. The subcommittee recommends that these instructions be prepared promptly and distributed to the regional staffs as soon as possible.

A separate PHS internal audit staff in Washington reviews the grant activity in the Office of Grants Management. This audit staff reviews the calculations of the State allotments under the formulas and also checks to see that the State plans have been reviewed by the professional staffs of the various divisions of the BSS.

The Director of the Audit Agency reports to the Comptroller of HEW (a position which recently has been elevated to a level comparable to that of Assistant Secretary), who in turn reports to the Secretary of HEW. The subcommittee considers that the present organization of the Audit Agency is satisfactory and meets substantially the recommendation of the independent advisory panel.

RECOMMENDATION M: THERE SHOULD BE INCREASED EMPHASIS ON AND CLOSER COORDINATION OF ENVIRONMENTAL HEALTH PROGRAMS

In November 1961 the special Committee on Environmental Health Problems, chaired by Paul M. Gross, presented a report to then Surgeon General Luther Terry which culminated a detailed study of the environmental health activities of the Public Health Service. The main conclusion of the Gross report was that:

> One of the factors missing in the current efforts of the [Public Health] Service is a place at which primary responsibility for the control of environmental hazards comes to a focus. The committee believes that immediate action should be taken to establish a center where the operational, research, and training programs of the Service in environmental health can be brought together.[81]

The committee recommended that a National Environmental Health Center be established "to implement effectively the development of a focal point within the U.S. Public Health Service for an enhanced and major national effort in environmental health" and further recommended that such Center be located in the Washington area. The Center was subsequently located, however, in the Research Triangle in North Carolina.

Subsequent developments also include (a) transfer of the Federal Water Pollution Control Administration, whose activities are centered in the Taft Sanitary Engineering Center in Cincinnati, out of the

[81] Report of the Committee on Environmental Health Problems, November 1961, p. 1.

Department of Health, Education, and Welfare into the Department of the Interior [82] and (b) authorization by Congress for construction of a new $25 million PHS Environmental Health Center near the University of Cincinnati campus. Thus not only has the primary recommendation of the Gross committee not been implemented, but it is now apparent that it will be more difficult than ever to achieve a centralized focus for a national environmental health effort. This makes it all the more imperative that the environmental health activities within the Public Health Service be coordinated as closely as possible, both with each other and with the related efforts of other agencies and departments, particularly the Food and Drug Administration and the Departments of Agriculture and Interior.

The developments subsequent to the Gross report also emphasize the importance of retaining the concept of environmental health as a health specialty, for two reasons: (1) To counter the potential fragmentation of the national environmental health effort and (2) to maintain a career identity which will serve to attract competent persons to work in this health field of rapidly increasing importance. The subcommittee was greatly concerned, therefore, when the proposed reorganization plan No. 3 indicated that the remaining environmental health divisions of the Bureau of State Services (after transfer out of the Water Supply and Pollution Control Division) would be "submerged" in a new PHS "Bureau of Disease and Injury Prevention and Control." The apparent deemphasis of environmental health appeared to be confirmed, in the opinion of many persons who contacted the subcommittee, by the fact that the word "environmental" did not even appear in the name of the proposed new bureau.

The issue of the Department's willingness to assume greater responsibility and leadership for a national environmental health effort was explored in great detail during the subcommittee's hearings, particularly by Congressman John J. Gilligan.[83] Both Secretary Gardner and Surgeon General Stewart assured the subcommittee of their awareness of and concern over the increasing difficulty of controlling environmental pollutants and contaminants and the need therefore of mounting a strong, coordinated national program to protect the population against disease or injury resulting from environmental hazards. The subcommittee endorses the planned emphasis on environmental health programs indicated by the Department's representatives and noted with approval the Department's subsequent action in changing the name of the proposed new Bureau to "Bureau of Disease Prevention and Environmental Control." [84] The subcommittee was particularly heartened by the recent assurance of Dr. Richard Prindle, the designated Chief of this new Bureau, that the planned consolidated facility on land donated by the University of Cincinnati "will be built up to a major national resource in the application of environmental health research and for the testing of criteria needed for control of environmental hazards." [85]

The subcommittee was advised that the Environmental Health Research Center in North Carolina would be primarily a facility for the conduct of basic research in environmental sciences (and would be administratively under the National Institutes of Health), whereas the new PHS Environmental Health Center to be constructed in

[82] Pursuant to reorganization plan No. 2 of 1966.
[83] Hearings, pp. 354–371.
[84] See app. B, chart 1.
[85] Environmental health letter, Aug. 1, 1966.

Cincinnati would be used to house what might be termed applied research in environmental sciences, similar to the type of activity carried on by the PHS for water pollution in the Taft Center prior to its transfer to the Department of Interior.

Because of the many questions left largely up in the air by the transfer, such as the future of the many PHS commissioned officers stationed at the Taft Center and the question of how the PHS would carry out its continuing responsibilities for the health aspects of water pollution control under the new arrangement, the subcommittee on August 19, 1966, made a brief 1-day tour of the Taft Center and other environmental health facilities in Cincinnati. While impressed by the cooperation being exhibited between the personnel of the Departments of HEW and Interior during the current difficult period of transition of the Taft Center, the subcommittee nevertheless became quite aware that many difficult personnel problems remain unresolved.

The most serious problem brought out by the subcommittee's visit, however, is the fact that transfer of the Taft Center to the Interior Department leaves the Department of HEW, and the PHS, with no central focus for the vital applied research and control aspects of the Nation's environmental health programs. The existence of this void emphasizes the need to build up the new PHS Environmental Health Center in Cincinnati into such a national focus for environmental health programs as quickly as possible. The subcommittee believes that it is particularly desirable that such a national environmental health center be established in Cincinnati in order to take advantage of the many environmental health resources—people, programs and facilities—already existing there and of the special emphasis placed by the University of Cincinnati on environmental health programs. In this regard it is pertinent to note the recent observation of Surgeon General William Stewart that "Cincinnati has become one of the air pollution control centers of the world." [86] The subcommittee strongly endorses, therefore, the intention of the Public Health Service, as expressed by Surgeon General Stewart, "to make our Center here [in Cincinnati] a major thrust in our total effort to protect and promote the health of the American people." [87]

It is essential that the activities of the Bureau in Washington and the research facilities in Cincinnati, North Carolina, West Virginia, and those related functions at the Communicable Disease Center in Atlanta be much more closely coordinated in the interest of overcoming the fragmentation of health services in the environment, which have been characteristic of past efforts in this field. It is also fundamental to a successful reorganization of the Public Health Service that a greater effort be made to mobilize and commit more of the resources of HEW to environmental health protection. This includes closer liaison with the Food and Drug Administration in pesticide surveillance, with the Office of Vocational Rehabilitation in connection with occupational health, and similar alinements.

In summary, the subcommittee recommends that the PHS: (1) Place increased emphasis on national environmental health programs, including programs for training environmental health specialists so as to preserve a visible career identity in this field, (2) proceed to establish as quickly as possible a national focus for applied research

[86] Remarks delivered to the Environmental Health Council of Cincinnati, Ohio, Aug. 19, 1966.
[87] Ibid.

and control programs in environmental health at the new PHS Envirnomental Health Center in Cincinnati and (3) make every effort to work out viable arrangements for retaining the services of the senior PHS water pollution specialists at the Taft Center in this important work.

RECOMMENDATION N: THERE IS A NEED FOR PERIODIC REVIEW OF HEW HEALTH PROGRAMS

One of the most important problems which became apparent in the course of the subcommittee's investigation results from the increasing number of "continuing" health programs administered by the Department of Health, Education, and Welfare. When a program is enacted on a continuing basis without periodic review thereafter by the enacting committees, this tends not only to decrease the frequency of subsequent reviews by the enacting committees to determine whether or not the program is accomplishing its purpose, but also to make it increasingly difficult for the enacting committees to evaluate the impact and interrelationships of proposed new health legislation on the existing program.

Appendix F of this report lists the 158 health grant programs administered by the Department of Health, Education, and Welfare. It will be noted that only 64 of these programs have authorizations which subject them to periodic review by the enacting committees, whereas 94, or a majority of them, are continuing programs which are subject only to annual budgetary reviews by the Appropriations Committees. One possible solution to this problem would be a careful review of all continuing programs by the enacting committees and establishment of 3- to 5-year authorizations for such of these programs as the enacting committees deem appropriate and desirable.

PART B—MANPOWER IN THE HEALTH SERVICES

Part B—Manpower in the Health Services

I. INTRODUCTION

Health management and the treatment of sickness is largely a service industry. People—their ability, numbers and work—provide the bridge between the availability of biomedical expertise and its consumers.

The adequacy of health care is affected by the quantity, quality, and types of workers that can be produced for health occupations. To a great degree, the success of the Nation's health effort as well as of Public Health Service programs rests upon adequate and sufficient health manpower and on the use to which it is put. Health manpower must occupy major departmental consideration in the years ahead.

Nearly 3 million persons, comprising about 4 percent of the total labor force of the United States, are employed in the health services. This represents an increase of 54 percent between 1950 and 1960, in contrast to a population increase of 19 percent. These health service employees include 30 percent of all biologists in the United States, 41 percent of all receptionists, 8 percent of all laundry workers, 8 percent of all librarians, 6 percent of all stationary firemen, 4 percent of all seamstresses, and a great variety of other occupations, such as carpenters, cooks, electricians, recreational workers, and meatcutters. There are some 40 occupational categories of health workers alone, and about 80 occupations in the civilian labor force that have 500 or more persons in health fields.[88] Since 1950, total expenditures for health care have tripled to approximately $40 billion, accounting for nearly 6 percent of our gross national product.[89] This rapid and extensive growth of the health industry has occurred in the absence of conscious planning, such that its services suffer serious redundancies, gaps, and conflicting interests. These deficiencies, discussed earlier in regard to intergovernmental relationships, have their counterparts in manpower development and utilization.

There is every indication that Congress and this committee will soon be asked to alleviate a health manpower crisis that has not yet been communicated in full dimension. The Hospital Construction and Modernization Act,[90] the Heart Disease, Cancer, and Stroke Act,[91] the Mental Retardation Facilities Construction Act,[92] and other health legislation enacted in the 88th and 89th Congresses will have a dramatic impact on manpower demand. The manpower implications of the 1965 Social Security Amendments,[93] as we are beginning to perceive through title XIX, promise to be very great indeed.

In addition, today's patients require much more in the way of services than did those of yesterday. Disease patterns are shifting

[88] Health Manpower Source Book, sec. 18, "Manpower in the 1960's." Public Health Service publication No. 263.
[89] "Economic Report of the President," January 1966, p. 102
[90] Public Law 88-443.
[91] Public Law 89-239.
[92] Public Law 88-164.
[93] Public Law 89-97.

from predominantly acute to predominantly chronic; complex surgical procedures requiring numerous specialists now reach cures formerly unattainable, or replace less exacting surgery formerly handled by fewer and less intensively educated physicians; diseases formerly unknown are being diagnosed and treated with increasing frequency. All of these developments imply more health personnel, better trained personnel, and in some cases new types of personnel. Successful treatment of the organic aspects of our most prevalent diseases, particularly heart disease and cancer, leads to new manpower challenges in maintaining a patient's functional capacities and achieving rehabilitation.

In many ways our environment has become increasingly hazardous and toxic. Radiological exposure, pollutants which contaminate our air and water, the symbiotic effect of crowded cities and high noise levels, and similar byproducts of civilization require increased research which will, hopefully, lead to prevention or treatment of the ills they produce. This, too, means medical and biomedical manpower in tasks not presently staffed.

We stand at a point in time when great achievements are possible. Application of current knowledge could prevent one-half the present loss of life through cancer.[94] Computers and other forms of automation promise revolutionary accomplishments in methods of diagnosis, treatment, and institutional organization. Recent developments in health care delivery have indicated ways to reach sick people previously unfamiliar with proper treatment. As these and other achievements are transformed from possibility to actuality, they will place additional demands on health manpower. Every gain in biomedical knowledge or in treating populations previously without health services is antecedent to new and more complicated needs requiring expanded health services and manpower, and new adjustments of manpower to efficacious application of those services.

Serious manpower shortages exist in most health occupations. These shortages have been cited consistently in expert and official reports for more than a third of a century. It is of direct concern to the Nation that these shortages have grown increasingly severe over the entire period, unabated by repeated warnings.

The shortage of physicians and related health workers was serious enough that the President's Commission on Heart Disease, Cancer, and Stroke established a special Subcommittee on Manpower. It was the conclusion of this subcommittee [95] that—

> The principal reason for our failure today to maintain the health of millions of people who are dying or incapacitated by these killers is the paucity of health manpower available to do the necessary work.[95]

Changes in medical care brought about through research efforts of recent years makes the demand for medical manpower "virtually insatiable," according to the Commission.

About half of all health workers have college degrees or are well trained. Because of the leadtime for medical education, in the Commission's opinion—

> The manpower needs for physicians and other highly skilled health personnel, caused by our expanding economy, our enlarging population, and our increased opportunities, are so great as to be unattainable during the next decade.[96]

[94] "Economic Report of the President," January 1966, p. 105.
[95] The President's Commission on Heart Disease, Cancer, and Stroke, "A National Program to Conquer Heart Disease, Cancer and Stroke." Report to the President, February 1965, p. 264.
[96] Ibid.

Accordingly, the Commission called for "an immediate and massive program" to create and enlarge all types of professional training schools.

The advent of Federal participation in health services delivery greatly exacerbates demand not only for physicians, but for all other health professions. However, it was not unforeseen. In delineating future policy in regard to physician training and utilization, a brief review of earlier studies is instructive.

II. MAJOR STUDIES OF MANPOWER REQUIREMENTS, 1930–64

Lee-Jones Study, 1930.[97]—Commissioned in connection with the Committee on the Costs of Medical Care, this study by Roger Lee and Lewis W. Jones was unique in its estimate of health needs on the basis of the amount of care required to provide adequate preventive, diagnostic, and curative services, according to medical custom of that period. The authors found the current supply of physicians to be approximately 13,000 short of need, and recommended revision of organization and economic arrangements to overcome the deficit.

Report of the Interdepartmental Committee To Coordinate Health and Welfare Activities, 1938.[98]—This Committee concentrated on maldistribution of physicians and nurses, and advocated a national health program to supply underprivileged areas and reduce economic barriers to care.

National Health Assembly, 1948.—Convened to assist Federal Security Administrator Oscar R. Ewing recommend plans for raising the national level of health over the following decade, the Assembly predicated physician needs on three bases: (1) maintenance of the 1940 ratio of physicians to population; (2) attainment nationally of the physician to population ratio then enjoyed by the 12 best States; and (3) volume of physicians' services needed to achieve the Lee-Jones standard of adequate treatment of all disorders. At the minimum, the assembly estimated demands for physicians by 1960 that would require at least 15,000 physicians more than current rates of supply would make available. The assembly recommended Federal assistance for construction and operation of medical schools, Federal scholarships for medical students, and incentives such as loan forgiveness and special fellowships to encourage better distribution of physicians. Federal funding through State health departments and schools of public health was also recommended to assist recruitment of public health personnel.

Ewing Report, 1948.[99]—Following on the assembly's deliberations, Ewing recommended a national program to meet the physician level then obtaining in the best 12 States (1 physician for every 667 persons, inter alia). However, this would require a 40 percent increase in medical school graduates by 1960, a goal that was already recognized as impossible. Consequently, Federal aid of at least $40 million per year at the onset, increasing over time, was recommended for construction of new medical schools, operation of teaching programs, and scholarship and fellowship programs for students. At the same time,

[97] "The Fundamentals of Good Medical Care." Chicago, University of Chicago Press, 1933.
[98] "The Need for a National Health Program." Report of the Technical Committee on Medical Care, Washington, D.C., 1938.
[99] Oscar R. Ewing, "The Nation's Health: A 10-Year Program." Report to the President, Washington, D.C., 1948.

better utilization of manpower was recommended by means of the development of group practice, wider use of paramedical personnel and extension of refresher and postgraduate courses.

Estimates of future physician requirements, 1949.[100]—Estimates of need for 1960 were predicated upon the bases of physician to population ratios in (a) the top one-fourth of the United States (146 per 100,000 population); (b) the top third (136 per 100,000) and the top half (118 per 100,000). On these bases, respectively 45,000, 34,000, and 17,000 additional physicians would be required; but even the lowest of these estimates was recognized as unattainable during the intervening period, considering the leadtime in expanding medical school output.

H.R. 5940, the Emergency Professional Health Training Act, 1949.[101]—This bill would have provided grants and scholarships for manpower training in medical, dental, and nursing professions. The Public Health Service testified "that the institutions which produce our highly skilled physicians, dentists, public health officers, nurses, and related workers in the field of health are confronted with financial problems so critical as to seriously threaten their ability to maintain the health of our people." This legislative proposal failed of approval.

Rusk Committee, 1951.[102]—Assuming only the maintenance of the 1949 physician-to-population ratio, maximum possible increases in medical school enrollment and acceleration of curriculums, this committee recognized a lingering deficit of about 22,000 physicians.

Magnuson Commission, 1952.[103]—To increase the supply of physicians and other health professionals to a level at which minimum standards could be met in all parts of the country by 1960, would require many years of effort, Federal aid to professional schools, federally supported scholarships, special programs to encourage the entry of Negroes into health work, and reorganization of health practice to effect more efficient utilization.

Bane Committee, 1959.[104]—Maintaining current levels of physician supply over the next 15 years would be so difficult a task as to make impracticable improvements in distribution, treatment in problems of aging and chronic illness, and resolution of problems concerning specialization and changing patterns of practice. Even this modest goal would require a 50-percent increase in medical school output, and the establishment of 20 to 24 new medical schools by 1975.

President's Commission on Heart Disease, Cancer and Stroke,[105] mentioned previously, noted the diminishing supply of "first contact" family physicians, and observed that the physician manpower crisis had reached the stage of requiring continued importation of foreign-trained physicians merely to maintain existing physician to population ratios over the next decade.

The Commission recommended a massive program of training in all health occupations, increased Federal appropriations for manpower, support of 2-year medical schools, Federal scholarships for

[100] Joseph Mountain, Elliott Pennel, and Anne Berger, "Health Service Areas· Estimates of Future Physician Requirements." Public Health Bulletin No. 305. Washington, D.C., 1949.
[101] Hearings before the Committee on Interstate and Foreign Commerce, 81st Cong., 1st sess., June 9. 1949. H. Rept. No. 1406, 81st Cong.
[102] Howard A. Rusk, chairman, Health Resources Advisory Committee, "Medicine, Mobilization, and Manpower," 1951.
[103] President's Commission on the Health Needs of the Nation, Building America's Health (vol. 2), "America's Health Status, Needs, and Resources," Washington, D.C., 1953.
[104] "Physicians for a Growing America." report of the Surgeon General's Consultant Group on Medical Education. Public Health Service Publication No. 709, Washington, D.C., 1959.
[105] Op. cit., n. 95.

medical and dental students, and the development of a manpower unit in the Public Health Service for continuous assessment of requirements. The recommendations have been substantially implemented during the 89th Congress.

Congressional action

There have been a number of studies conducted over the years into health manpower problems. The subject of health has been within the jurisdiction of the House Interstate and Foreign Commerce Committee since 1798, and the committee has enacted considerable legislation since that time having to do with the public health.

In 1953 the parent committee of this subcommittee conducted extensive hearings into the subject of health in the United States, including problems of health manpower. In addition, the subject of medical manpower has been considered in connection with legislation enacted by the Congress, such as the Health Professions Educational Assistance Act of 1963, and amendments thereto in 1964 and 1965 extending and expanding the scope of the program; the Nurse Training Act of 1964; the Graduate Public Health Training Amendments of 1964; the Health Amendments of 1956, the Health Research Facilities Amendments of 1960, and extensions thereof in 1965; the Allied Health Professions Personnel Training Act of 1966; and numerous other items of legislation.

III. MANPOWER PROJECTIONS, 1965–75

Appropriations for the national health manpower effort of the Public Health Service approximate $300 million in fiscal year 1967, largely in the form of grants for construction and improvement of training facilities, scholarships, and loans. Additional sums have been appropriated for manpower development in research and basic sciences, and for medical manpower development by other departments.

Recently enacted bills have substantially increased Federal authorization for health manpower programs. Little is known as to the probable impact of this authorization on manpower supply, since it is not yet fully funded. Projections beyond 1975 would therefore be difficult at this time.

However, projections are available to 1975 for physicians and dentists, and to 1970 for nurses, taking into account current plans for the expansion of training facilities. These projections are valid generally under current authorization, in view of the educational leadtime necessary to train personnel for the professional categories indicated.

Supply

At the close of 1965 there were 305,115 physicians in the United States, including 13,027 doctors of osteopathy, 6,000 graduates of Canadian medical schools, and 38,500 graduates of other foreign medical schools. These data represent an overall physician-to-population ratio of 153 per 100,000 population. At the same time there were 621,000 nurses, or an average of 319 per 100,000 population. As of July 1, 1965, there were 109,301 dentists in the United States, or an average of 56.2 per 100,000 population.

Assuming a fairly constant supply of foreign-trained licentiates, we should expect a total of at least 357,000 and possibly 360,000 physicians by 1975, or roughly 154 to 156 per 100,000 population (table 1).[106]

TABLE 1.—*Physician supply in 1975 based on number of graduates of U.S. medical and osteopathic schools at current planned growth*

Year	Graduates of U.S. medical and osteopathic schools	New licentiates graduated from Canadian and foreign schools [1]	Deaths among those in the profession	Physicians (M.D. and D.O.)	
				Number as of Dec. 31	Rate per 100,000 persons [2]
1963	7,627	1,651	3,700	289,200	149
1964	7,700	1,600	3,800		
1965	7,890	1,600	3,900	300,300	150
1966	7,965	1,600	4,000		
1967	8,010	1,600	4,100		
1968	8,065	1,600	4,200		
1969	8,190	1,600	4,300		
1970	8,300	1,600	4,400	327,900	153
1971	8,580	1,600	4,500		
1972	8,805	1,600	4,600		
1973	8,955	1,600	4,700		
1974	9,035	1,600	4,800		
1975	9,185	1,600	4,900	356,900	154

[1] Licentiates graduated from Canadian schools estimated at 200 per year, with balance graduated from foreign facilities.
[2] Population: 1963, 194,117; 1965, 199,542; 1970, 214,570; 1975, 232,221.

Source: Health Manpower Source Book, sec. 18, "Manpower in the 1960's," p. 38; Public Health Service publication No. 263.

In view of recent authorization, approximately 4,200 dental students should graduate in 1975, bringing our supply of dentists from its present 108,000 to about 121,000. However, this will represent a decrease from 55.4 dentists per 100,000 population to about 53.5 per 100,000 in 1975 (table 2).

TABLE 2.—*Dentist supply in 1975 based on number of graduates of U.S. schools at current planned growth*

Year	Dentists		Graduates of U.S. dental schools [2]	Deaths among those in the profession
	Number as of July [1]	Rate per 100,000 persons [1]		
1963	105,550	55.7	3,243	4,055
1964			3,200	
1965	107,935	55.4	3,205	
1966			3,215	
1967			3,340	10,620
1968			3,375	
1969			3,395	
1970	113,845	54.5	3,410	
1971			3,540	
1972			3,590–3,725	11,195
1973			3,620–3,830	
1974			3,645–3,990	
1975	120,365–121,055	53.3–53.6	3,665–4,200	

[1] Population: 1963, 189,375; 1965, 194,671; 1970, 208,996; 1975, 225,870.
[2] Excludes Puerto Rico.

Source: Health Manpower Source Book, sec. 18, "Manpower in the 1960's," p. 52; Public Health Service publication No. 263.

[106] The Council on Medical Education of the American Medical Association recently projected a total of 360,000 physicians by 1975.

There are more uncertain variables with regard to nursing education, causing projections to be less precise. In general, however, it is expected that the number of professional nurses available will increase from the present level of 580,000 to approximately 680,000 by the beginning of 1970 (table 3). Qualifications to this projection are indicated below.

TABLE 3.—*Professional nurse goal for 1970*

Year	Estimated number of nurses in practice on Jan. 1	Graduates of U.S. schools of nursing	Net losses among those in the profession [1]	Net additions to the nurse supply
1962	550,000	31,186	22,000	9,200
1963	559,200	32,398	22,300	10,100
1964	569,300	33,400	22,800	10,600
1965	579,900	33,200	23,200	10,000
1966	589,900	34,200	23,600	10,600
1967	600,500	52,000	24,000	28,000
1968	628,500	50,200	25,100	25,100
1969	653,600	53,000	26,200	26,800
1970	680,400			

[1] Based on (*a*) losses through death or inactive status among those in the profession, and (*b*) gains through return to practice of nurses formerly inactive or addition of foreign-educated nurses. Computed at 4 percent, adapted from NLN method.

Source: Health Manpower Source Book, sec 18, "Manpower in the 1960's," p. 64. Public Health Service Publication No. 263.

Inadequate information exists for projections of manpower supply in the medical specialties, nursing specialties, allied health professions, technical fields, and health aide trades.

Regional maldistribution

At the end of 1965 the District of Columbia, New York, and Massachusetts showed ratios of 373, 217, and 204 physicians per 100,000 population respectively. At the other end of the spectrum, Alaska, Mississippi, and Alabama showed ratios of 71, 74, and 80 physicians per 100,000 population respectively.[107] Within States metropolitan areas enjoy higher proportions of physicians to population than rural and semirural areas, and within cities suburban areas fare better than poverty areas. Some parts of the country, such as certain Appalachian regions and some southern regions, are completely without physician services; while other sections are served only by physicians three or four decades out of medical school.

The number of active dentists varies (as of July 1963) per 100,000 population from 78, 67, and 66 respectively in the District of Columbia, New York, and Oregon, to lows of 19, 24, and 25 respectively in South Carolina, Mississippi, and Georgia[108] (fig. 2). Similarly, the ratio of nurses per 100,000 population varies (as of 1962) from 526, 502, and 491 in the District of Columbia, Massachusetts, and New Hampshire to 120, 142, and 157 in Arkansas, Mississippi, and Alabama[109] (fig. 3).

[107] Health Manpower Statistics Branch, National Center for Health Statistics, "Health Manpower in the United States, 1965." Public Health Service Publication No. 1509 (1966).
[108] Health Manpower Source Book, sec. 18, "Manpower in the 1930's," p. 45. Public Health Service Publication No. 263.
[109] Id., p. 56.

FIGURE 1: PHYSICIAN-POPULATION RATIOS IN EACH STATE

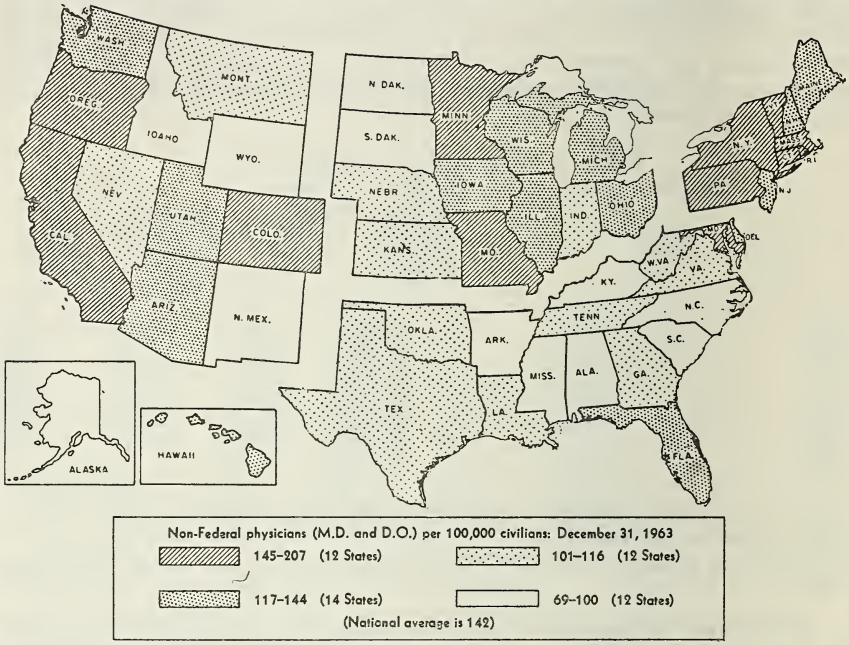
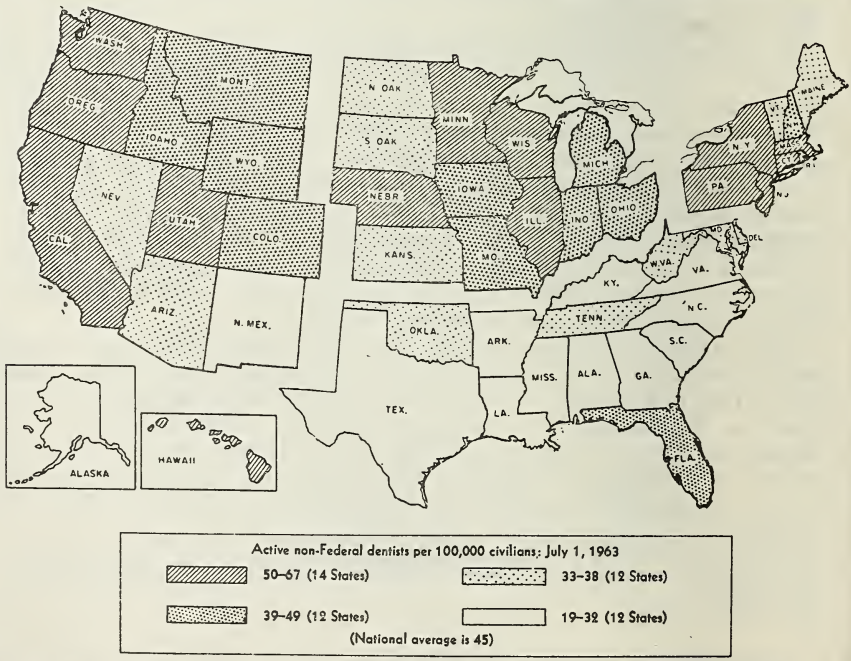
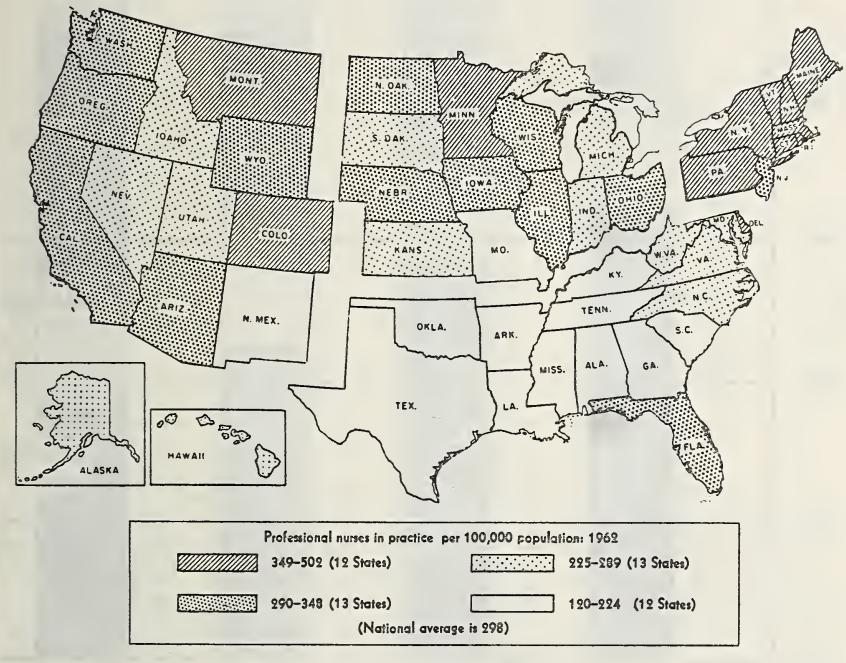


FIGURE 2: DENTIST-POPULATION RATIOS IN EACH STATE



Source: Health Manpower Source Book, Section 18, Manpower in the 1960's, p. 22 (Fig. 1) and p. 44 (Fig. 2). Public Health Service Publication No. 263.

FIGURE 3: PROFESSIONAL NURSE-POPULATION RATIOS IN EACH STATE



Source: Health Manpower Source Book, Section 18, Manpower in the 1960's, p. 55. Public Health Service Publication No. 263.

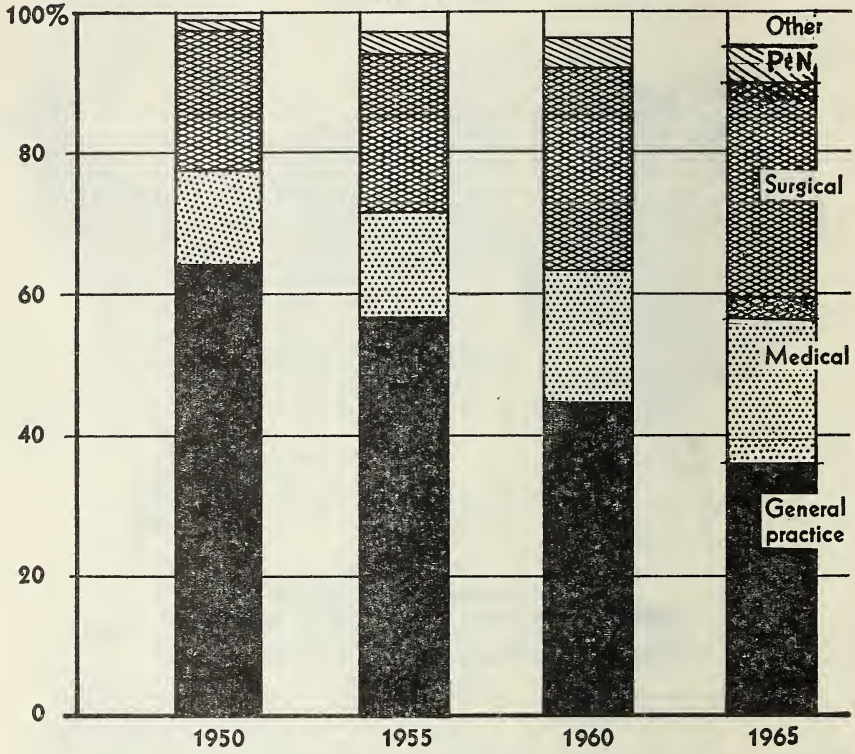
There has been little change in regional distribution of health manpower over the past 25 years.

General practitioners and specialists

In 1950, 64 percent of the M.D. physicians in private practice regarded themselves as general practitioners, and 36 percent as specialists. By 1965 these proportions were exactly reversed.

While the proportion of general practitioners has dropped from 64 to 36 percent, the proportion of M.D.'s in medical specialties has risen from 13 to 21 percent, in surgical specialties from 20 to 33 percent, in psychiatry and neurology from 2 to 5 percent, and in other specialties from 1 to 5 percent (fig. 4).

FIGURE 4: SPECIALIZATION OF PHYSICIANS IN PRIVATE PRACTICE (M.D. only)



Source: Manpower Statistics Branch, National Center for Health Statistics.

These data reveal a phenomenon which is increasingly felt if not seen by American patients; that is, the gradual extinction of the general practitioner. Fifteen years ago there were 95,000 family physicians in the United States, or 1 for every 1,600 Americans. By 1970 there will be only 49,000, or 1 for every 4,379 Americans. Only a fraction of this loss will be made up by internists. As against an anticipated loss of some 13,000 general practitioners between 1965 and 1970, the number of internists will increase by only 6,000.[110] There is no indication that this trend will change within the foreseeable future, given the present pattern of physician specialization.

General practitioners and internists are "first contact" physicians, the traffic directors of the medical world. Their net reduction in ranks portends longer queues, hastier service, and less accurate diagnoses for all Americans unless some imaginative new solutions can be devised to meet these problems.

Shortages of physician manpower

It will be noted that the slowly rising ratio of physicians to population indicated in table 1 is predicated on an anticipated stable influx, over the decade from 1965 to 1975, of about 1,600 graduates

[110] Data from the National Disease and Therapeutic Index, Ambler, Pa.

from foreign medical schools. This expectation does not seem realistic, however, since the admission of foreign-trained licentiates reached its zenith in 1959, and now appears to be receding (table 4).

TABLE 4.—*Licentiates added to practice in the United States, 1950–64*

Year	Licentiates		Percent of licentiates foreign-trained
	Total	Foreign-trained	
1950	6,002	308	5.1
1951	6,273	450	7.2
1952	6,885	569	8.3
1953	7,276	685	9.4
1954	7,917	772	9.8
1955	7,737	907	11.7
1956	7,463	852	11.4
1957	7,455	1,014	13.6
1958	7,809	1,166	14.9
1959	8,269	1,626	19.7
1960	8,030	1,419	17.7
1961	9,080	1,580	17.4
1962	8,887	1,357	15.3
1963	9,077	1,451	16.1
1964	8,996	1,306	14.5

Source: Health Manpower Statistics Branch, National Center for Health Statistics.

Absent a marked increase in its medical school vacancies, the United States remains highly dependent upon a continued supply of graduates from abroad. As indicated in table 5, a sudden depletion of this supply could deleteriously affect our ratio of physicians to population and possibly cause it to diminish. Moreover, the loss of physician manpower has already become a matter of Government concern in countries from which we draw most heavily. It cannot be assumed that measures will not be taken abroad to reduce the volume of emigrating physicians.

TABLE 5.—*Physician supply in 1975 based on numbers of graduates of U.S. medical and osteopathic schools at current planned growth and new licentiates of Canadian and foreign schools at 3 levels*

Year	Graduates of U.S. schools	If 1,600 graduates of Canadian and foreign schools are licensed annually after 1965		If 1,000 graduates of Canadian and foreign schools are licensed annually after 1965		If no graduates of Canadian and foreign schools are licensed after 1965	
		Number	Rate	Number	Rate	Number	Rate
1965	7,890	300,300	150	300,300	150	300,300	150
1966	7,965						
1967	8,010						
1968	8,065						
1969	8,190						
1970	8,365	327,900	153	324,900	151	319,900	149
1971	8,580						
1972	8,805						
1973	8,955						
1974	9,035						
1975	9,185	356,900	154	350,900	151	340,900	147

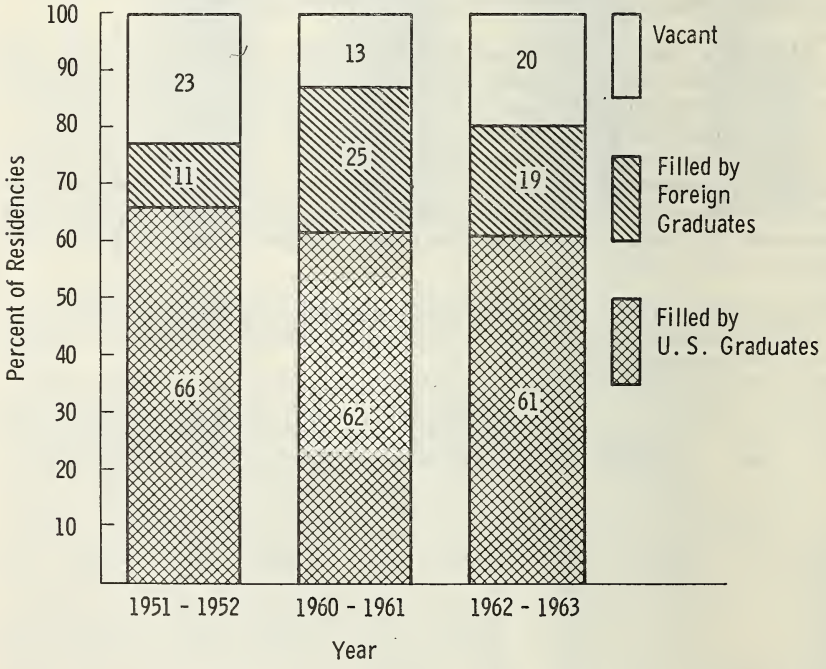
Source: Health Manpower Source Book, sec. 18, "Manpower in the 1960's," p. 39; Public Health Service publication No. 263.

Furthermore, graduates of foreign medical schools do not enjoy a fluid labor market, and are therefore unlikely to contribute to the alleviation of regional disparities in physician supply. They do not

benefit from reciprocal licensing between States, as do domestically trained physicians. Indeed, four States refuse to license them at all.

The extent to which the United States depends for health services upon foreign-educated physicians is brought home more forcefully when we examine training programs in the U.S. hospitals. In 1960–61 U.S. hospitals offered 12,547 training programs for interns, of which fewer than three-fourths were filled. Of the interns assigned, fewer than 7,000 were trained in the United States. This year only slightly more than half the existing internships were filled, nearly two-sevenths of them by foreign-trained physicians.[111] At the residency stage, only three-fifths of the vacancies during the academic year 1962–63 were filled by graduates of U.S. medical schools (fig. 5). In general, foreign-trained residents tend to accumulate in municipal hospitals. In 1964, for example, 40 of the 44 residents in Lincoln Hospital, a municipal hospital in New York City, were foreign trained. At the same time, only half the applicants to American medical schools are accepted for training, although there is no showing that those rejected lack ability.

FIGURE 5: PERCENT DISTRIBUTION OF OCCUPANCY OF RESIDENCIES (U.S.A., SELECTED YEARS, 1951–1963).



Source: American Medical Association, Directory of Approved Internships and Residencies, 1963, Chicago, 1963.

[111] New York Times, Mar. 15, 1966.

These observations are germane to future planning for medical school capacity in the supply of physician manpower. Realistic appraisals of health manpower resources should eliminate consideration of foreign trained physicians for planning purposes.

National goals for nursing: The Nurse Training Act of 1964

It was the "best judgment" of the Surgeon General's Consultant Group on Nursing that the national goal for nurses be set at 850,000 professional nurses by 1970. This recommendation envisioned approximately 200,000 nurses at the baccalaureate level and another 100,000 with graduate preparation.[112]

A need for an additional 350,000 practical nurses and 300,000 nursing and psychiatric aids was also suggested.

Recognizing that these goals were not feasible, the group reduced its recommendation on Federal effort for professional nurses to an achievement of 680,000 by 1970.[113] The lower goal did not represent a revision of need, but rather the recognized limit on the potential supply of students and on the potential capacity of the Nation's nursing schools. Even if attained, the lower goal would leave an unfilled need estimated at 170,000 nurses in 1970.

However, one-fifth of our nurses are presently working only part-time: in 1964 (latest available figures), 132,000 out of 582,000. Attainment of an adequate supply of nurses by 1970 would therefore require graduation of 100,000 annually by 1969. But last year there were only 33,200, for a net gain of about 10,000 (since roughly 23,000 left the profession). This pattern has been holding firm for the past 5 to 10 years.

The Nurse Training Act of 1964 was passed pursuant to the group's recommendation. It authorized a 5-year $287,630,000 program, of which $85 million would be authorized for low interest, partially forgivable student loans. This loan feature is a key aspect of this legislation.

The loan authorization permits individual student loans to a maximum of $1,000, at 3 percent on the unpaid balance, and specifies forgiveness up to half the principal and interest for employment in a public or nonprofit institution on completion of studies. As a practical matter, only the loans to baccalaureate and graduate students would reach the maximum; those for diploma programs would probably average half that amount.

One published economic appraisal of the act's features [114] indicates that it can attain its objective; i.e., the consultant group's modified goal, only if loans under the act are made entirely to marginal students (those who would not have entered nursing school without the loan). Even if such selection were possible, this would ignore the undeniable financial needs of the nonmarginal nursing students. The author's estimate in view of these needs was that the act's goals would fall short of attainment by one-fourth to two-thirds the desired number of graduates. Hence a considerable portion of the act's authorization for expansion and improvement of diploma schools would not be used, further inhibiting future enrollment.

[112] "Toward Quality in Nursing," op. cit., p. 19.
[113] Id., p. 23.
[114] Donald E. Yett "The Nursing Shortage and the Nurse Training Act of 1964" 19 Industrial and Labor Relations Review 190-200 (January 1966).

Assessing these considerations, the author advised the addition of a large nursing school scholarship program aimed particularly at associate degree and diploma levels.

This subcommittee is satisfied that the Department is implementing the consultant group's recommendations to the extent of its own manpower and appropriations, and that it is administering the Nurse Training Act satisfactorily. Nevertheless, it is clear that the Nation's requirements for nursing services are not being met through existing programs. As noted below, the evidence is unavoidable that nursing shortages remain severe throughout the Nation, with the result that patients in many hospitals are subjected to unnecessary risk. It is therefore incumbent upon the Department to explore new solutions and additional incentives for improved nurse recruitment and retention; to promote more efficient utilization of professional nursing services through job analysis, increased employment of nursing aides and improvement of nursing facilities; and to seek further means of meeting the nursing needs of our sick.

Health manpower deficiencies: An overview

For three decades the ratio of physicians to population has remained the primary index used in planning future physician requirements. But technological changes during that period have made the ratio increasingly unreliable as a measure of patient need. In terms of methodological developments now anticipated in delivery of medical care, the ratio promises to be even less useful in determining future supply goals.

We are left, consequently, with only vague notions of the extent to which physicians' services are short. We know, for example, that there are already insufficient general practitioners to afford every American a 2-hour annual checkup;[115] but we have no data that would tell us how many physicians and other medical team members would be required for maximal utilization of preventive measures available to us today. We know that there are not enough psychiatric workers available to treat all of our disturbed children,[116] but we have no guidance as to the true dimension of this deficiency. We know that instrumentation now in existence or being perfected could forestall many of the 400,000 strokes which occur each year,[117] but we have no data on how many and what sorts of health personnel would be required to effect this protection. We have no clear idea, in terms of health manpower, what kind of staffing would be necessary, and in what organizational patterns, to reach the millions of Americans who are now without access to proper medical care.

A similar paucity of information creates difficulties in establishing priorities for public investment with respect to recruitment and training of nurses. In general, we know that one-fifth of the Nation's budgeted positions for nurses are vacant. This represents an increase in vacancies from about 5 percent in 1941 and 10 percent in the early 1950's, despite efforts of the Cadet Nurse Corps, the Hill-Burton Act, the mental health training grant program, and the nurse traineeship

[115] Norman Holly, "The Economics of American Medicine," 54 American Economic Review 1189 (December 1964).
[116] "Major Ailments Afflict One-Third of Poor Children," Medical World News, Nov. 5, 1965, p. 65.
[117] Economic Report of the President, January 1966, p. 105.

program. At the present time there are budgeted vacancies for at least 75,000 registered nurses and 25,000 practical nurses.[118]

However, we do not have refined profiles of nurse shortages in specific areas, nor data as to their meaning in terms of health care. If such information is revealed at all, it is usually tucked away in learned journals. Thus, we learn through one professional journal that 60 to 70 percent of the general staff nursing positions in New York City are vacant; that in one of its 400-bed municipal hospitals there are only 31 registered nurses available for direct patient care on a regular basis, and only 4 during the evening shift; that such shortages have resulted in diabetic patients missing insulin shots and critically ill patients not getting antibiotics.[119] From a newspaper we learn of a hospital's shortage so severe that "critically ill patients * * * have been denied adequate care for as long as 8 hours." [120] We do not know what is happening in many other cities, or in rural areas.

Hospital certification under Public Law 89–97, the Social Security Amendments of 1965, requires (inter alia) the provision of "24-hour nursing service rendered or supervised by a registered professional nurse, and * * * a licensed practical nurse or registered nurse on duty at all times." [121] According to the Social Security Administration, several hundred hospitals in the United States are unable to meet even this minimal standard.

There are many indicators to suggest that health manpower planning procedures fail to take account of the actual health needs of the Nation. It is reported that one-sixth of all inductible young men would be found unfit for medical reasons to serve in the Armed Forces; and that the majority of rejectees upon whom this estimate is based appear to be "victims of * * * insufficient health services." [122] Of those who are called for induction and rejected for reasons of health, it appears that few receive adequate corrective treatment.[123]

Nearly 7 percent of the school dropouts applying for Neighborhood Youth Corps enrollment cite health problems as the major reason for their withdrawal. The subcommittee was advised that no further information is available as to the specific health problems of these young people, or of the treatment needed.[124]

Thirty-one percent of the 1,442 preschool children examined in connection with Project Headstart in Boston exhibited major physical defects or emotional problems of clinical significance. The physical conditions covered a wide range, from cardiovascular disease to retardation resulting from metabolic disturbances. In the opinion of a Headstart official, the mental conditions discovered represented a caseload greater than the city of Boston could handle, if standard mental health techniques were employed. It was further estimated that the incidence of such occurrences would reach 45 to 50 percent

[118] Philp D. Bonnet, M.D., president, American Hospital Association, "Health Manpower Needs and Requirements," Training Health Service Workers: The Critical Challenge (Proceedings of the Conference on Job Development and Training for Workers in the Health Services, Washington, D.C., Feb. 15, 1966), p. 23.

[119] Alonzo Yerby, "The Disadvantaged and Health Care," 56 American Journal of Public Health 5, 8 (January 1966).

[120] Donald Zochert, "Shortage of Nurses a Critical Situation," Bergen (N.J.) Record, Mar. 9, 1966.

[121] Public Law 89–97, sec. 1861(e)(5).

[122] The President's Task Force on Manpower Conservation, "One-Third of a Nation: A Report on Young Men Found Unqualified for Military Service."

[123] George James, "Poverty as an Obstacle to Health Progress in Our Cities," 55 American Journal of Public Health 1757, 1762 (November 1965).

[124] Communication from the Assistant to the Administrator, Neighborhood Youth Corps, U.S. Department of Labor, May 25, 1966.

among the city's "invisible poor." A survey of Boston school dropouts by Dr. Thomas Cone of the Children's Hospital Medical Center revealed a similar range of conditions, only several years advanced.[125]

Nineteen of the thirty-five children in a class of slow learners in Washington, D.C., were discovered last April to be there because of poor eyesight, not lack of ability; but the city's referral clinic was unable to treat them within the school year. According to the school superintendent, "Many more children than we know are trapped in classes for slow learners because of undetected or untreated health problems." [126]

Mental retardation is significantly more prevalent in those population groups where maternal care is frequently inadequate; [127] yet with the current rate of obstetrical training, it is estimated that half the babies delivered by 1980 will be cared for on the wards of municipal and community hospitals, where obstetrically disadvantaged mothers today experience twice the rate of infant mortality and three times the rate of physically and mentally retarded children as normally occur in voluntary hospitals.[128] There is no estimate of the obstetrical services needed for our growing population, and no planning for comprehensive prenatal and nurse-midwife facilities and services.

The average cost of treating a case of rheumatic heart disease is $22,000. It is estimated that 75 percent of all new cases could be prevented through streptococcal infection surveillance among schoolchildren, at a cost of $7.15 per child.[129] But we lack enough pediatricians, public health personnel, nurses and other workers to detect and treat the streptococcal infections which, if ignored, lead to valvular disease of the heart.[130]

The President's Commission on Heart Disease, Cancer, and Stroke noted that many cases of surgically curable cervical cancer cannot be treated because of insufficient cytological technicians to staff screening programs.[131] In fact, medical technology disciplines have been overlooked generally in health manpower planning:

> It has been estimated that by 1975 there will be a need for 172,000 additional medical technicians for laboratory work alone. If needs for other types of health technicians were added, the requirement becomes staggering. However, no good estimates of need are available. Studies have been made in recent years of the needs for physicians, dentists, and nurses, but the health technician field has been largely ignored.[132]

For 10 years the National Committee for Careers in Medical Technology has made intensive efforts to attract science students to careers in these disciplines, but the numbers recruited have remained comparatively stable.[133]

This has been attributed to lack of medical technologists on college science faculties, and dearth of scholarships for medical technology students as against an abundance for those in basic sciences.[134]

[125] Medical World News, Nov. 5, 1965, p. 64.
[126] Washington Post, Apr. 16, 1966, p. 1; and Apr. 17, 1966, p. B–1.
[127] Report to the President, A Proposed Program for National Action to Combat Mental Retardation, Washington, October 1962.
[128] Louis Hellman and Francis O'Brien, "Nurse Midwifery—An Experiment in Maternity Care," 24 Obstetrics and Gynecology, 343, 346 (September 1964).
[129] Milton Saslaw, Angel Vieta and Robert Myerburg, "Cost of Rheumatic Fever and of its Prevention", 55 American Journal of Public Health 429, 433 (March 1965).
[130] The President's Commission on Heart Disease, Cancer and Stroke, op. cit., vol. II, p. 273 (February 1965).
[131] Ibid.
[132] Id., Vol. I, p. 62.
[133] Peter G. Meek, "Health Manpower", 39 Hospitals 67 (Apr. 1, 1965).
[134] J. A. Cunningham, "Meeting the Demand for Technically Trained Personnel in the Medical Laboratory", 18 Bulletin of the College of American Pathologists 82 (May 1964).

One authority estimates a need for some 25,000 additional registered medical technologists.[135]

The projected need for physical thereapists is at present only two-thirds filled. There are fewer than three-fourths the required number of occupational therapists, and half of them work only part time.[136]

The manpower needs in surgery have never been accurately assessed. Available statistics—

> contribute little or nothing to answering questions as to how well the needs of the country are being met in the various specialties within the surgical field. Nor do they provide any guides for medical educators in the education and training of surgeons for the future.[137]

This lack of information is due partly to inadequate data relative to surgery in many hospitals, and to lack of criteria for determining the optimum number of physicians to be engaged in these specialties. Today only half of all operations are performed by board-certified surgeons. About one-fifth of them are performed by general practitioners with no specialized training.[138] An increase of 100 percent in the number of certified surgeons would be necessary in order for operations to be performed exclusively by them. This would, in turn, require considerable expansion of current programs for the training of academic surgeons.

The increasing complexity and duration of modern surgery has raised the requirements for anesthesiologists. However, the number of physicians in residence for anesthesiology has fallen off from its peak in 1959; and this does not take into account the normal attrition rate which has not yet become operative, since nearly all anesthesiologists who have been trained are still living. Currently only 40 to 45 percent of the estimated need for clinical anesthesiologists is being met.

> Consequently, there still remains a significant mortality and morbidity which constitutes an important national health problem. * * * Although the exact number of anesthetic deaths from maladministered anesthesia is not definitely known, it has been estimated between 10,000 and 30,000 per year. Morbidity associated with anesthesia is equally important.[139]

Today there are about 7,500 anesthesiologists in clinical practice. At least 25,000 would be required to manage present requirements for surgical and obstetric anesthetics. The shortage is so acute that many hospital directors have contracted for anesthesia services with independent "full service" groups, who in turn hire their own physicians and nurses to administer the services.[140]

At the same time, most medical school departments of anesthesiology face critical shortages of academic personnel. This shortage will be exacerbated by further dilution to be occasioned in the provision of anesthesiology faculty in new medical schools now being planned. Present achievements in this field will not be maintained through 1975 unless there is drastic and immediate action.[141]

The services of radiologists are being denied to some patients because of manpower shortages. To alleviate the present deficit would require

[135] Health is a Community Affair. Report of the National Commission on Community Health Services, Bethesda, Md., May 9, 1966, p. 137.
[136] Id., p. 136.
[137] Bulletin of the American College of Surgeons, November–December 1963, p. 355.
[138] Ibid.
[139] Correspondence from John J. Bonica, M.D., President of the American Society of Anesthesiologists, June 17, 1966.
[140] New York Times, May 16, 1966, p. 1.
[141] Statement by Michael E. DeBakey, M.D., chairman of the Department of Surgery, Baylor University College of Medicine, July 21, 1965.

almost twice as many radiologists as are presently available; that is, the training of 1,500 radiologists each year for the next 10 years, a nearly impossible feat.[142] Earlier this year the National Advisory Committee on Radiation advised the Public Health Service to undertake, inter alia, extensive training and research development programs in several radiological sciences, to initiate standards for personnel qualifications and other matters in connection with the handling of radioactive materials, and immediately to strengthen its programs in the radiological sciences by unifying administrative direction.[143]

Our parent committee has previously recognized that advances in medicine and increasing demand for health services require additions to the supply of health manpower, both in numbers and in new skills.[144] New diagnostic techniques will, in turn, stimulate demand for the services of virologists, cytotechnologists, immunologists, optometrists, mycologists, and a wide variety of other specialists, technicians, and aids.

Nor does the training of public health personnel seem responsive to the needs of this generation. Change in the delivery of health services, currently a matter of prime importance in health circles, will impose major responsibility for comprehensive planning and coordination on departments of health at all levels of Government within the near future. Few departments, however, are staffed with the special personnel required to assume responsibility of this breadth.

> The single fact is that very few people are being prepared in schools of public health today, or anywhere else, who could justifiably be presented to a community as qualified for this job. * * * [I]n our view the proper qualifications for a person capable of heading such an enterprise may be quite unlike the prototype of the public health officer we are accustomed to thinking of. We think it is reasonable to suppose that the larger and more complicated the system, the more important will be preparation in the social sciences, particularly in public administration. A medical education alone is clearly not sufficient preparation for the job.[145]

The Second National Conference on Public Health Training observed that vacancies exist in about 10 percent of the budgeted positions for professional State and local public health personnel. Over the past decade these public health departments have failed to grow with population, and in some areas have declined in absolute numbers. Simply to keep pace with projected population growth they must prepare approximately 17,000 additional public health personnel by 1970.[146]

Furthermore, these departments are only barely maintaining standards in the personnel they do recruit. The percentage of professional full-time personnel considered to possess the educational background required for their positions rose from 49 percent in 1958 to only 51 percent in 1963.[147]

In its 1965 policy statement the American Public Health Association advised that "In view of important public health implications of recent antipoverty and other Federal legislation, official State and local health agencies should (1) review priorities to make room for

[142] Russell H. Morgan, M.D., Chairman of the National Advisory Committee on Radiation, quoted in Medical World News, June 3, 1966, p. 30.
[143] National Advisory Committee on Radiation, Report to the Surgeon General on Protecting and Improving Health Through the Radiological Sciences, April 1966.
[144] Allied Health Professions Personnel Training Act of 1966. Report of the Committee on Interstate and Foreign Commerce on H.R. 13196, 89th Cong., 2d sess. (June 16, 1966), p. 5.
[145] "The Education of Public Health Personnel: A Pilot Study." Report of the Joint Committee on the Study of Education for Public Health. Washington, October 1965.
[146] Report of the Second National Conference on Public Health Training, Aug. 19–22, 1963, pp. 9–10.
[147] Ibid.

new programs while maintaining essential activities; (2) modify personnel functions and develop new kinds of health manpower; and (3) be receptive to and cooperate with new partner agencies in promoting the public health.

The Under Secretary of Health, Education, and Welfare has testified on the necessity of training public health personnel for the new kind of programs and the new kinds of interests developing at State levels, and on the difficulty that some States may experience in obtaining such personnel.[148] Part of this difficulty could be overcome by the establishment of a National Health Academy for inservice, refresher, and continuation training of persons engaged in public health work (such as is provided, for example, by the National War College for the Armed Services) for the purpose of keeping public health personnel up to date on the latest developments in their professional areas. (See recommendation A below.)

It is imperative that accurate assessment be made of the types and numbers of health personnel required for comprehensive and efficient preventive, diagnostic, and rehabilitative treatment in terms of the incidence of affliction and of available resources; and that thorough analysis be given to the determination of working relationships between these personnel for maximal utilization of manpower training effort.

IV. FRAGMENTATION OF THE DEPARTMENT'S HEALTH MANPOWER EFFORT

With increasing legislative recognition of health manpower needs, new bills are enacted and existing laws amended to provide additional training resources for the health professions. These manpower provisions have been distributed for administration among the bureaus and activities to which they relate in the Department, rather than being consolidated in an overall manpower effort. As a consequence, training and training facilities construction grants derive from numerous sources; statistical and other manpower data is collected and evaluated in various places; and manpower planning is fragmented among many offices and administrators. Among the bureaus and offices active in health manpower activities are:

Office of the Surgeon General

The Division of Public Health Methods develops estimates of health manpower needs according to long-range projections of socioeconomic, environmental, and population characteristics, and develops plans to meet the requirements estimated.

The Division of Health Mobilization assists States and communities in organizing health personnel for effective implementation of emergency health survival plans, and develops preparedness programs for civilian health manpower under all conditions of national disaster.

The Health Manpower Statistics Branch of the National Center for Health Statistics surveys data from primary and secondary sources to determine the numbers, geographic location, age, and other characteristics of health manpower in various fields; makes short-range projections of manpower to be available in these fields; prepares publications on health manpower resources for programs of the Public Health Service, other Government agencies, national professional and

[148] Hearings before the Committee on Labor and Public Welfare, U.S. Senate, on S. 3008 (Mar. 16, 1966).

voluntary agencies, and other members of the health community; and provides consultative assistance to such programs and agencies regarding methods of obtaining or interpreting manpower statistics.

The Financial Management Branch of the National Center for Health Statistics conducts a junior professional training program, both for health statisticians newly appointed to the Center and for foreign nationals already working in the field of health statistics.

The Office of Personnel has general administrative responsibility for formal and inservice training of Public Health Service employees, including the commissioned officer residency deferment program and the commissioned officer student training and extern program.

The National Library of Medicine

The National Library of Medicine conducts training programs for medical literature indexers, searchers, and subject heading specialists; and supports the formal training, through traineeships and fellowships, of students of medical librarianship, biomedical science information, information management and processing technology, biomedical science writing and editorial work, and the history of the life sciences.

Bureau of State Services (Community Health Divisions)

The Division of Community Health Services conducts a health manpower program through its Manpower Resources Branch, pursuant to the heart disease, cancer, and stroke legislation of 1965, which assesses and projects medical and paramedical manpower needs and resources. (This program is reviewed in greater detail below.) The Division also administers loans to students of medicine, osteopathy, dentistry, optometry, podiatry, and pharmacy.

The Division of Nursing administers the training grant provisions of the Nurse Training Act of 1964, and collaborates with other Public Health Service units in carrying out student loan programs and in funding grants to schools of nursing for improvement in nurse training and for the construction, expansion, or renovation of nurse training facilities. This Division also conducts a continuing review of national nursing needs, and provides consultation for the development of program requirements.

The Division of Dental Health assesses and projects dental manpower and facilities needs and resources, conducts workshops on local dental health programs and conducts research on programed instruction and curriculum development for dental education.

The Division of Hospital and Medical Facilities administers the planning and construction provisions of the Hill-Burton program for construction or modernization of hospital and medical facilities; the construction, renovation, and expansion provisions of the Health Professions Educational Assistance Act for schools of medicine, osteopathy, dentistry, podiatry, pharmacy, and public health; and provisions of the Mental Retardation Facilities Construction Act for provision of comprehensive services to the mentally retarded having as their primary focus the training of professional and technical personnel needed for optimum management of mentally retarded patients.

The Division of Accident Prevention develops and conducts seminars and short courses for professional personnel at State and local levels, and supports the development and expansion of accident pre-

vention curricula in educational institutions and in training programs for professional health personnel in State and local agencies.

The Division of Chronic Diseases supports agencies and organizations in the development of training programs designed to increase the number of personnel with specialized knowledge and skills in chronic disease categories and to increase the competence of those already working in these areas. The Division also provides training grants in the fields of mental retardation, cancer control, and the neurological and sensory diseases.

The Communicable Disease Center supports and conducts training programs for the dissemination of its research results and applications to scientific methods and techniques to professional and subprofessional health workers in State and local departments, other Federal agencies, professional and industrial organizations, and foreign countries.

The Division of Medical Care Administration forecasts and analyzes medical care administration manpower needs, develops educational and training programs for professional and ancillary health and administrative personnel needed for medical care administration activities, and supports training and retraining programs in this field.

The Division of Grants Management represents the Bureau's effort to coordinate administration, policy, and procedures for nonresearch training grants, as well as its formula and project grants. The Division administers grants to assist the training of cytotechnicians, dental students, public health professional personnel, senior clinicians, neurological and sensory disease specialists, mental retardation personnel, and professional nurses. It also funds institutional improvements for the teaching of medicine, osteopathy, dentistry, optometry, podiatry, pharmacy, nursing, and public health; and maintains liaison on training grants with the Division of Research Grants, National Institutes of Health.

Bureau of State Services (Environmental Health Divisions)

The Division of Air Pollution supports curriculum development and training programs for skilled personnel in air pollution work.

The Division of Environmental Engineering and Food Protection conducts a training program directed to the development of professional and technical capabilities in scientific and engineering fields relevant to its work.

The Division of Occupational Health conducts and supports short courses in selected aspects of occupational health for employees of occupational health and industrial hygiene units, industry, and insurance companies.

The Division of Radiological Health supports curriculum development and training in radiological health and conducts short courses in technical disciplines essential to radiological health work.

The Office of Resource Development supports a research training program directed to the development of professional capabilities ni scientific and technological areas related to environmental health sciences.

Bureau of Medical Services

The Division of Hospitals conducts programs of internships in medicine, pharmacy, dentistry, and dietetics; residency programs in

various fields; and training programs in nursing, medical record library science, social service, physical therapy, occupational therapy, and laboratory and X-ray technology.

The Division of Indian Health conducts a school of practical nursing and a school for dental assistants; and residency programs in preventive medicine, general medical practice and pediatrics.

Welfare Administration

The Children's Bureau provides training for various professional disciplines involved in the care of multihandicapped children, such as occupational, physical, and speech therapists; and, pursuant to the 1965 Social Security Amendments, administers grants to institutions of higher learning for the training of professional personnel such as physicians, psychologists, nurses, dentists, and social workers for the care of crippled, mentally retarded, and multiple handicapped children. The Bureau also participates in the development of standards for the training of professional personnel in several activity areas.

Vocational Rehabilitation Administration

The Office of the Assistant Commissioner for Research and Training administers long-term, short-term, and in-service training grants and research fellowships in fields related to the rehabilitation of disabled persons, such as rehabilitation medicine, orthopedic surgery, ophthalmalogy, neurology, nursing, prosthetics-orthotics, physical therapy and speech pathology-audiology; and short-term intensive training grants to support training for the improvement of rehabilitation knowledge and techniques.

Office of Education

The Bureau of Elementary and Secondary Education administers grants for fellowships and traineeships to prepare professional personnel to teach handicapped children.

The Bureau of Research supports research activities in problems of handicapped children and youth.

Other

There are grants for the training of research manpower available through various Institutes of the National Institutes of Health; and manpower training programs in pathology, radiology, pharmacology and several basic sciences through the Bureau of Scientific Research of the Food and Drug Administration.

In addition, several other departments of the Government conduct or finance training for manpower in fields of health; for example, for the training of health aides through the Office of Economic Opportunity's mobilization for youth program, and of various subprofessional categories by the Department of Labor pursuant to the Area Redevelopment Act and the Manpower Development and Training Act.

V. THE MANPOWER RESOURCES BRANCH OF THE DIVISION OF COMMUNITY HEALTH SERVICES

The Second National Conference on Public Health Training recommended the establishment of a health manpower unit in the Public Health Service, closely related to operational programs and training

activities, to be responsible for: "(a) Collection and analysis of pertinent data on a continuing basis; (b) conduct and support of studies and demonstrations related to training and recruitment; and (c) dissemination of information on all aspects of health manpower." Among the tasks anticipated for such a unit were regular assessment of national needs and resources for health manpower, the support and conduct of effectiveness studies on training programs for the preparation and recruitment of health personnel, and the stimulation and support of recruitment demonstration programs.[149]

Such a unit was included in the Department's budget request on three occasions, but was twice written out: in 1962 by the Department itself, and in 1963 by the Bureau of the Budget. Bolstered by strong support in the report of the President's Commission on Heart Disease, Cancer and Stroke and the President's 1965 message,[150] the need for such a unit was communicated to Congress.

Recommendation 27 of the President's Commission recommended the establishment of a health manpower unit in the Bureau of State Services comparable to the research manpower unit in the National Institutes of Health, to be responsible for continuous assessment of national manpower requirements for health services.[151]

Such a unit would have the following responsibilities: (1) To develop baseline information on medical manpower and analyze its meaning; (2) to develop national goals relating to medical manpower and resources; (3) to conduct and support studies and demonstration related to determining manpower needs, defining specific problems, and recommending improved training and recruitment programs to overcome these manpower problems; and (4) to disseminate information on all aspects of health manpower.

The President's Commission recommended an appropriation of $500,000 during the unit's first year, increasing to $1 million by the fifth year. An appropriation was requested in accordance with the recommendation,[152] and 15 positions were budgeted and distributed among five offices according to the organization chart opposite.

Thus organized, the manpower unit was to provide an "overview" of the Nation's health manpower problem and to give attention "to the many areas in which little or nothing is being specifically dealt with by other activities."

To date the manpower resources program has been primarily concerned with the organization of a staff knowledgeable in the areas of recruitment, education, and utilization of health manpower. A few studies have been initiated and others are planned. It has yet to tackle the very complex issues related to the formulation of a national health manpower policy. The location of this program in the proposed Bureau of Health Manpower in a reorganized Public Health Service suggests an early attention to this priority concern. The subcommittee hopes that the response is equal to the challenge.

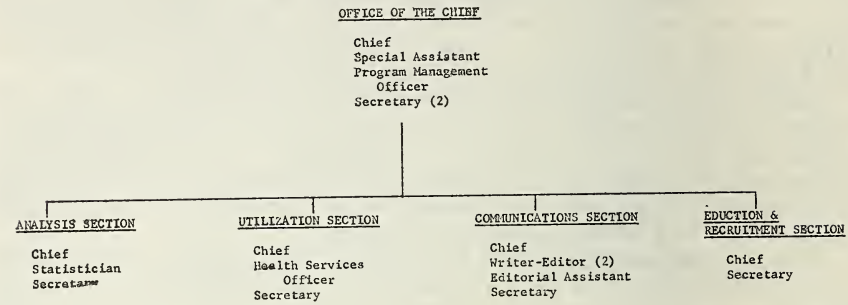
[149] Second National Conference on Public Health Training, "Report to the Surgeon General," September 30, 1963, p. 14. Public Health Service publication No. 1087.
[150] "Advancing the Nation's Health," in a message from the President of the United States, 89th Cong., 1st sess., Jan. 7, 1965, p. 9.
[151] The President's Commission on Heart Disease, Cancer, and Stroke, op. cit., Vol. I, pp. 61-62.
[152] Hearings before the Subcommittee of the Committee on Appropriations. U.S. Senate, 89th Cong., 1st sess., on H.R. 10586 (Aug. 25, 1965), p. 127.

PUBLIC HEALTH SERVICE

BUREAU OF STATE SERVICES

DIVISION OF COMMUNITY HEALTH SERVICES

Manpower resources program



VI. FINDINGS AND RECOMMENDATIONS

RECOMMENDATION A: THE HEALTH MANPOWER EFFORT OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE SHOULD BE COMBINED IN ONE BUREAU; ESTABLISHMENT OF A NATIONAL HEALTH ACADEMY

The fragmentation evident in the divers manpower activities enumerated above serves to blunt the impact of present efforts and to expend appropriations for less than optimal return. The critical mass necessary to convert manpower recruitment, training and utilization into effective health programs will not be achieved until these particles are brought together.

The aggravating effect of fragmentation was referred to repeatedly by expert witnesses before our committee. As delineated by Dr. James L. Dennis, director of the University of Oklahoma Medical Center and dean of the School of Medicine—

> The shortage in health manpower is further aggravated by an almost unbelievable fragmentation, duplication, and multiplicity of health services and programs located in an ever-increasing number of agencies, bureaus, and divisions, all of whom currently appear to be in a competitive race to develop crash programs for manpower production, a belated recognition of the statement that health services are trained people.[153]

We are informed by the Department that its proposed Bureau of Health Manpower will comprise the present functions of the Division of Hospital and Medical Facilities (which administers the Health Professions Educational Assistance Act), the Division of Nursing (which administers the Nurse Training Act) and the Division of Dental Public Health and Resources (which administers the dental provisions of the Health Professions Educational Assistance Act).[154] But as enumerated above (p. 83 et seq.), more than 2 dozen divisions, bureaus, and administrations within the Department are involved in manpower efforts of varying magnitudes. Furthermore, resolution of health manpower problems in several occupational areas require activity which could not be specifically foreseen in previous legislation,

[153] Hearings, p. 197.
[154] Id., p. 363.

and investigations of matters that may possibly need to be encompassed in future legislation. The mission of the Bureau of Health Manpower should not be confined to problems of the past, nor limited merely to the scope of manpower activity currently engaged in by the three divisions mentioned.

The subcommittee was assured by Secretary Gardner that the proposed Bureau—

> will have the primary concern for building an adequate supply of health manpower for the Nation. It will be responsible for projecting manpower needs and developing programs to meet them. It will serve as a central point of information for educators, administrators, and others involved in the training of professional and subprofessional health workers.[155]

The committee is of the opinion that this goal can be achieved only if the proposed Bureau is truly the central focus of the Department's total health manpower effort, rather than merely the amalgamation of those manpower activities now being pursued in Divisions of Hospital and Medical Facilities, Nursing, and Dental Public Health and Resources.

As a useful adjunct to the proposed Bureau in its health planning, the Department should consider establishment of a National Health Academy. The short supply of health professionals with health planning competency within the public health services has been recognized for some time. In reference to environmental health personnel, for example, the National Commission on Community Health Services has observed the lack of personnel and resources among public health departments necessary to control effectively "the full scope of today's health hazards" and to improve the environment of their communities.

> The fact is that many communities are not covered by local health departments employing full-time public health officers, and supporting staff. Also, many State and local health departments do not have the support, from appropriations and law enforcement procedures, that is needed to maintain a clean and safe community environment.[156]

In his statements in connection with S. 3008, "The Comprehensive Health Planning and Public Health Service Amendments of 1966," the Under Secretary of the Department of Health, Education, and Welfare envisaged—

> A great need to train personnel for the new kinds of programs and the new kind of interests that States have. There may be difficulty in getting trained personnel in some of the smaller States and in some of the States with special problems. * * * [T]he Surgeon General has to assist in training this type of personnel and make them available to the States.[157]

A National Health Academy would assist the Secretary in carrying out the purposes of currently proposed legislation to encourage and facilitate the development of comprehensive planning to meet current and future manpower needs.

Equally important functions for such an Academy would be operations planning for the Department's total health manpower effort, research on applications of existing automation to manpower problems, demonstrations on efficient manpower utilization, inservice and

[155] Id., p. 352.

[156] "Health is a Community Affair" Report of the National Commission on Community Health Services, op. cit., p. 145.

[157] Hearings before the Committee on Labor and Public Welfare, U.S. Senate, 89th Cong., 2d sess., Mar. 16, 1966.

specialty training for public health personnel (especially in problems of environmental health), and locus for "roundtable" discussions and conferences of State and local health officers. As the site of intergovernmental conference, the Academy would be particularly useful in the coordination of manpower activities at various governmental levels and across geographic regions.

RECOMMENDATION B: THE PUBLIC HEALTH SERVICE SHOULD DEVELOP IMPROVED INDICES RELATED TO HEALTH CARE NEEDS IN ITS PLANNING FOR HEALTH MANPOWER REQUIREMENTS

The irony that permits poverty to flourish amidst affluence has its counterpart in health manpower services. We are blessed with a higher ratio of physicians to population than most advanced countries. Since 1950, despite significant population growth, that ratio has been kept firm. Yet we know there are serious shortcomings in individual medical attention; and we know there are large segments of the population that receive no medical attention at all.[158] The ratio of physicians to population, the standard reference of health care for the past two decades, fails to inform us properly of these deficiencies for purposes of health manpower planning.

To assume that a constant ratio signifies maintenance of a certain standard of health care is to ignore medical progress over those decades; progress which requires more exacting levels of performance, and higher concentrations of health workers to perform certain tasks. It further overlooks the serious deficiencies that existed in the base year of any comparative ratio.

The achievements of modern medicine benefit every American at some point in his life. Today's physician is considerably more knowledgeable and skillful than those of preceding generations. Assisted by the remarkable postwar progress of his art, he is able to conserve life and rehabilitate useful activity more efficiently than has been possible at any previous time in history.

But modern medical achievements imply greater specialization, and consequently more intensive use of health personnel. Mere maintenance of existing ratios, or insufficient increases in ratios, means eventual rationing of services. However, the American people have too much invested in the achievements of modern medicine, both through direct public investment in research and in support of the milieu of practice in the United States, to allow their being rationed on any basis other than medical need. In terms of planning for today's requirements, therefore, ratios of physicians to population are faulty guides as measures of adequate care.

For example, foreign trained licentiates are obscured in such ratios; they afford no information on where these licentiates were trained, what sort of work they are doing, or where they are doing it. The ratio of physicians to population has other faults as an index of manpower utilization. Statistically, it equates the ability and energy of an 80-year-old retiree with those of a recent medical school graduate. Occupationally it fails to differentiate between the services of research, administrative, and practicing physicians. Pathologically it misses the significance of evolving demand and techniques to treatment.

[158] Dr. Julius Richmond, program director for Project Headstart in the Office of Economic Opportunity, informed our subcommittee, for example, that only about 8 percent of the children now given health care under the project previously enjoyed continuing health care. Hearings, pp. 213, 229.

Similar complaints might be registered in connection with estimates of need for nurses, allied health professionals, technicians and aides. All are projected from base years or existing compositions which may themselves represent large inadequacies.

Several economic analyses indicate manpower shortages not revealed in conventional indexes. One study, for example, observed a substantial physician shortage indicated by income disparities between physicians and other professional workers, which has been attributed to restrictions on entry into medical training.[159] The existence of sizable vacancies in salaried positions where salaries compare favorably with declared mean incomes, such as in prepaid group practices and public health appointments, is also an indication of shortage that the ratio fails to reveal. Another is the extent of unserviced and underserviced population, considering the occupational mobility of health workers.

More meaningful indexes should be employed as criteria of health care adequacy in the determination of national policy. Ideally such indexes should take into account the incidence of treatable conditions, the extent and types of treatment recommended, staffing patterns of health teams needed to render such treatment, and medical services necessary for recommended levels of diagnosis and prevention. Automation renders this ideal more easily attainable today than ever before. Currently, for example, Tufts Medical School is employing computer analysis in determination of treatment expenditure for a variety of conditions encountered in its Columbia Point project, in a low-income section of Boston.

Additional measures have also been suggested; for exemple, a time estimate of treatment by physician sample superimposed on a disease incidence profile.[160] The National Planning Association uses a technique for estimating both dollar and manpower requirements for 1975 based on a translation of effective demand, assuming a narrowing of "the gap between the potentialities of the modern health technologies and the availability of medical care for most Americans".[161] Econometric models might also be developed for this purpose.[162]

Estimates of the manpower necessary for provision of health services are of primary importance, both for the immediate period and in the future. However, this subcommittee is of the opinion that no acceptable theoretical or practical framework for the analysis of manpower requirements is yet in use. Congress must be served with realistic estimates of need and more graphic accounts of existing deficiencies in health care if it is to assist in mounting a cogent attack against the unseen enemies that sap the strength of American productivity.

[159] Milton Friedman and Simon Kuznets, "Income from Independent Professional Practice" (New York, National Bureau of Economic Research, 1954), p. 133; Friedman, "Price Theory: A Provisional Text" (Chicago, Aldine Press, 1962), pp. 159–161; see also David Blank and George Stigler, "The Demand and Supply of Scientific Personnel" (New York, National Bureau of Economic Research, 1957), p. 24.

[160] George W. Bachman, "A Method for Measuring Physician Requirements", 158 Journal of the American Medical Association 375 (June 4, 1955).

[161] Leonard Lecht, "The Dollar Cost of Our National Goals" (Washington, National Planning Association, 1965).

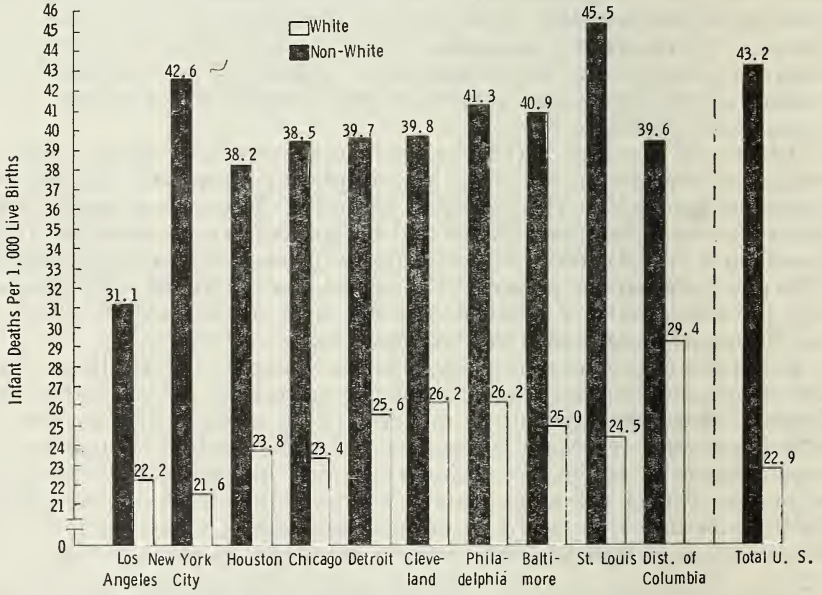
[162] For example, C. L. Chaing, "An Index of Health: Mathematical Models" (Washington, National Center for Health Statistics, series 2, No. 5, May 1965).

RECOMMENDATION C. THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE SHOULD ENCOURAGE AND ASSIST IN THE DEVELOPMENT OF NEW AND NEEDED TYPES OF HEALTH OCCUPATIONS, AND OF THE INSTITUTIONAL INNOVATIONS NECESSARY TO THEIR EFFICIENT ABSORPTION AND UTILIZATION ON HEALTH TEAMS

Numerous studies testify to the fact that traditional forms of health care delivery fail to reach large segments of our society, and are only inefficiently useful to others. For many Americans this failure exists from birth to death.

We know, for example, that perinatal mortality is twice as high among nonwhites as it is among whites, three times as high for the poor as for the affluent, and twice as high in municipal and community wards as in voluntary hospitals; that these high mortality rates are accompanied by three times the "normal" rate of prematurity and of physical and mental retardation among the survivors;[163] and that from this group of poor starters we will find the most obstinate and unnecessary health problems of the future.

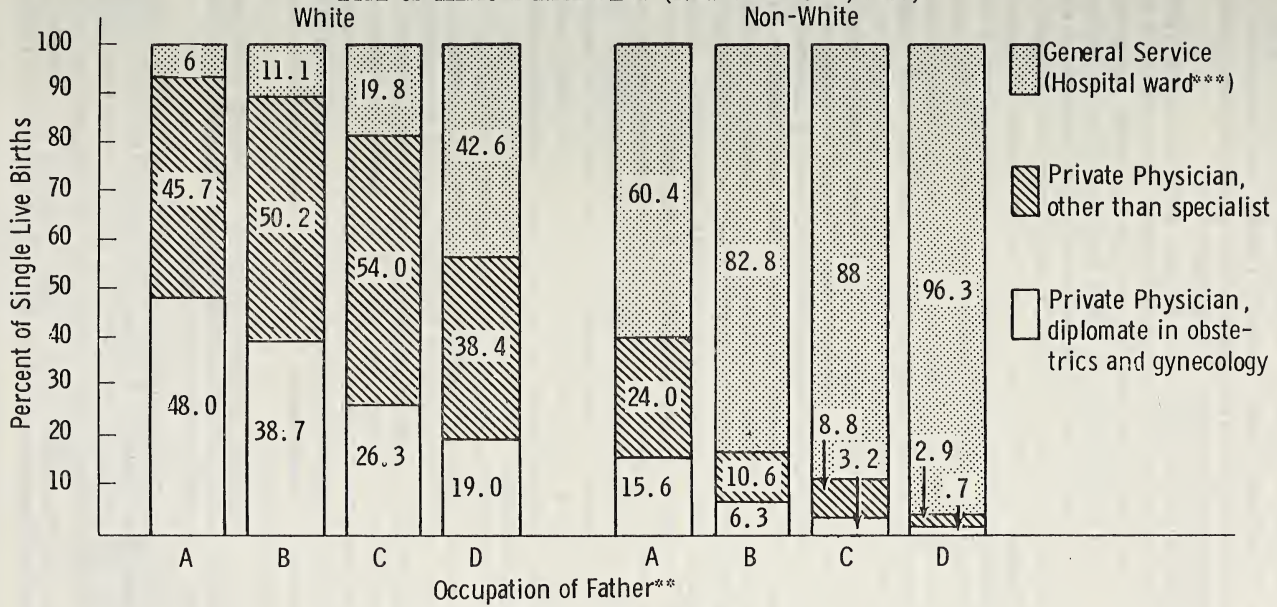
FIGURE 6: INFANT MORTALITY RATE BY RACE (10 CITIES AND UNITED STATES TOTAL, 1960).



Source: "Geography of Infant Mortality," Public Health Reports, March 1963, Vol. 78, No. 3, p. 270.

[163] Louis Hellman and Francis O'Brien, "Nurse Midwifery—An Experiment in Maternity Care," 24 Obstetrics and Gynecology 343, 346 (September 1964).

FIGURE 7: PERCENT DISTRIBUTION OF SINGLE LIVE BIRTHS IN EACH OCCUPATIONAL GROUP OF FATHER FOR EACH RACE* BY TYPE OF MEDICAL ATTENDANT (NEW YORK CITY, 1955).



* Data for the Puerto Rican population are not included in this chart.

** Occupation of Father: A = Professional, managerial, technical B = Clerical, sales
C = Craftsman, operatives, service D = Laborers and other

*** 4 percent of General Service births occurred at home or in an ambulance.

Source: S. Shapiro, H. Jacobziner, P. M. Densen, and L. Weiner, "Further Observations on Prematurity and Perinatal Mortality in a General Population and the Population of a Prepaid Group Practice Medical Care Plan," American Journal of Public Health, September 1960, Vol. 50, No. 9, p. 1315.

We know that one-third of our children in poverty suffer from preventable or treatable conditions which will eventually lead to blindness, deafness, chronic illness, or early death; and that many of them remain untouched by medical care, even when dwelling within the shadow of our greatest medical institutions.[164]

We know that persons in families with annual incomes below $2,000 incur twice as many bed-disability days, 1⅔ times as many work-loss days, and 1½ times as many hospital days as persons with incomes of $10,000 or more;[165] that the Negro disabled worker suffers more from environmental diseases and is hospitalized over longer periods of time than the white disabled worker; and that the gap between Negro and white illness and mortality rates is increasing rather than decreasing.[166]

The health problems of these groups are not their's alone. We all pay the bill: whether it be in medicare charges at $40 per day, or in overtaxed health manpower and medical facilities, or in loss of human productivity, or in the uncontrolled forces of physical and mental disease. Undetected or uncorrected vision defects, for example, are cited by the chief clinical psychologist of Sing Sing Prison in relation to educational failure and antisocial behavior;[167] and poor vision was determined by the 1960 White House Conference on Children and Youth to be a contributing factor to the learning and reading difficulties accounting for four-fifths the delinquency studied. Treating the sick is not merely humanitarian; it is provident in the preservation of social values and in the conservation of health resources. And in the long run, it is less expensive to detect and treat early.

This Nation is now committed to the goal of adequate health care for all citizens, to the extent of our capacity to provide it.[168] The nature and extent of present impediments to that goal have inspired considerable thought and comment by leading physicians, social scientists, and public health officials as to reorganization and improvement of health care delivery.

Furthermore, it is widely recognized that merely increasing the numbers of persons in existing health occupation categories is an incomplete solution both for manpower deficiencies and for adequate delivery of medical benefit. Indeed, deficiencies in the highest professions have reached the point where, because of the leadtime necessary for training, they cannot be overcome under present systems of service delivery as far into the future as it is possible to estimate. In this respect, the President's Commission on Heart Disease, Cancer, and Stroke recently concluded that—

> We must immediately undertake programs designed to provide semiskilled assistants, since these can be trained more rapidly than can specialists, and they can be used to augment the effectiveness of specialists.[169]

New forms of health care and medical teamwork will allow many time-consuming unskilled duties to be absorbed by health aides. New attempts to bridge gaps between patient and medical treatment will require the use of health aides in the community, in primary care units, and in medical complexes. However, there is as yet no significant effort underway in the Department of Health, Education, and Welfare

[164] "Major Ailments Afflict One-third of Poor Children," Medical World News, Nov. 5, 1965, p. 64.
[165] National health survey, U.S. Public Health Service.
[166] George James, "Poverty as an Obstacle to Health Progress in Our Cities," 55 American Journal of Public Health 1557, 1762 (November 1965).
[167] F. R. Hilpert, "Poor Vision—Clue to Juvenile Delinquency?" Family Weekly (Processing and Books, Inc., Chicago), Aug. 30, 1964.
[168] President's message on health, March 1966.
[169] "A National Program to Conquer Heart Disease, Cancer, and Stroke," op. sit., vol. II, p. 264.

that would facilitate the recruitment, training, and utilization of this category of health personnel.

Another critical need for which the Department has no program is obstetrical workers below the level of obstetricians. Although the overall rate of infant salvage has improved in the United States, our rate of improvement has been much slower than that of other countries. From 1950 to 1964 the United States slipped from 7th place to 16th place among nations of the world, and our trend is still downward.[170] Furthermore, infant mortality rates in 7 of our 10 largest cities actually increased within this period, by 5 to 25 percent.[171]

It is reported that the United States was ranked among the "underdeveloped countries" in a recent international congress on obstetrics.[172] Our poor reputation in this field is frank recognition that large segments of the American public have been omitted from the current gains in obstetrical technique. Furthermore, it is estimated by one expert that the projected growth in the number of obstetricians is only canceling out the decline in general practitioners who were formerly instrumental in providing obstetrical care.[173]

The key to low infant mortality rates, and therefore lower rates of mental and physical retardation among children, is adequate prenatal and maternity care.[174] It is significant that most of the nations now enjoying a more favorable rate than ours operate trained nurse-midwife facilities and training programs. It has already been demonstrated that similar services can achieve similar results in the United States. Nurse-midwives trained at the State University of New York (downstate)—King's County Hospital Center, for example, have achieved an overall infant mortality rate of 9.6 per 1,000 live births. This rate is two-fifths that of our national average, and only about one-fourth those found in some of our disadvantaged areas.

One appropriate activity for the research staff of the proposed Bureau of Health Manpower would therefore seem to be in the development of prenatal and maternal care patterns that would reduce manpower demand in future by reducing infant mortality and its accompanying retardation.

There are other areas where development of new and needed types of professional services could have significant impact on manpower problems. The Royal College of Physicians & Surgeons in Canada, for example, has recently considered the advantages of differentiating medical teaching as to family physicians, specialist-consultants and clinical scientists for specific roles on health teams.[175] Similar suggestions, for the training of primary (first contact), secondary (consultant) and tertiary (clinical scientist) care physicians, have been

[170] In 1964 we were outranked by Sweden, Netherlands, Norway, Finland, Iceland, Denmark, Switzerland, Australia, New Zealand, England and Wales, Japan, Czechoslovakia, France, Taiwan, and the Jewish population of Israel. Preliminary data indicate that East Germany and Canada also ranked ahead of the United States in 1965. At the present time Sweden's infant mortality rate is half that of the United States. (While there is some variation in reporting bases between nations, the difference in relative position is significant.)

[171] Arthur Lesser, "Closing the Gaps in the Nation's Health Services for Mothers and Children," 41 Bulletin of the New York Academy of Medicine 1249 (December 1965).

[172] Roul Tunley, "The American Health Scandal" (New York, Harper & Row, 1966), p. 38.

[173] Hellman and O'Brien op. cit., p. 346.

[174] Cf. Report to the President, "A Proposed Program for National Action to Combat Mental Retardation." Washington, D.C., October 1962.

[175] The Royal College of Physicians & Surgeons of Canada, "The Clinical Teaching Unit as an Effective Organization for the Education of Residents Under Changing Medico-Socio-Economic Circumstances." (Mimeographed, Sept. 11, 1965.)

advanced in this country as ways to improve manpower utilization.[176]

The training of new categories of health workers, the institutional settings needed for their optimum utilization, and their role on the health team should be fully explored in the search for solutions to health manpower problems.

RECOMMENDATION D: THE PUBLIC HEALTH SERVICE SHOULD EXERCISE INITIATIVE IN SECURING EARLY AGREEMENT BETWEEN INTERESTED PARTIES REGARDING STANDARDS OF ACCREDITATION, CERTIFICATION AND TRAINING CURRICULA NECESSARY TO THE RECRUITMENT OF HEALTH TECHNICIANS AND HEALTH AIDES

Manpower shortages can be alleviated through effective utilization of available health personnel, continuous evaluation of the use of manpower, and retraining for new health occupations.[177] Effective utilization, in turn, implies allocation of work functions for maximal output on the basis of the training and experience necessary to their performance. It is well agreed that many routine functions now performed by physicians and nurses could be carried out by persons with less training, and that many additional functions are reallocable through application of available automation.

At the present time, however, several of the auxiliary health occupations are lacking in training standards, and others are languishing for want of standardized curricula and job orientation. There is some suggestion also that rigidity in present certification requirements may be inhibiting recruitment of capable workers.[178]

For example, increasing professionalization of nurses demands developing a corps of health aides to assume duties for which nurses are presently overtrained. However, there exists at the present time no agreement on training or job requirements for such workers, nor on any procedure for their certification.

Substantial numbers of persons have been partially trained for this occupational level, who are lost to health professions through absence of program and facilities for further development. Every year more than 10,000 health technicians are released from the armed services.[179] These persons have trained and functioned in a wide range of specialties, including medical, dental, optical, cast, operating room, preventive medicine, neuropsychiatry, social work, physical therapy, electroencephalography, X-ray, and many others. But no one knows what becomes of the thousands that are released, and only one program is known to exist to supplement their training and experience so that certification may be accomplished for comparable civilian occupations.

Through its mobilization for youth program the Office of Economic Opportunity is currently training a number of formerly unemployed high school graduates and "dropouts" to function as medical record specialists, laboratory aides, nursing aides, and in similar essential

[176] Kerr L. White, "Organization and Delivery of Personal Health Services: Public Policy Issues" (unpublished paper for the seminar on health policy, Institute for Policy Studies, Washington, D.C., May 31, 1966).

[177] "Health Is a Community Affair." Report of the National Commission on Community Health Services (Bethesda, Md., May 1966), p. 133.

[178] Philip D. Bonnet, M.D., president, American Hospital Association, "Health Manpower Needs and Requirements," in Training Health Service Workers: The Critical Challenge (proceedings of the Department of Labor-HEW Conference on Job Development and Training for Workers in Health Services, Washington, D.C., Feb. 15, 1966), p. 25.

[179] Information supplied to the subcommittee by the Department of Defense.

tasks. For some time their trainees have been exemplary in their performance of such functions in clinics and hospitals, such as the Gouveneur Ambulatory Care Clinic of Beth Israel Hospital in New York. But these people continue to perform, at $1.25 per hour, work identical to that performed by their tutors for two or three times that salary. There exists no "career ladder" by which they might be certified, through continued formal training programs or otherwise, for the work which they are now performing. They are therefore "tied" to the institution in which they trained, unable to qualify for similar positions elsewhere and economically discouraged from remaining where they are. Where this is the case, in the opinion of one noted economist "you don't have a true training program. Your efforts will be largely wasted." [180]

Absent any private or public body to effect the continued accommodation of such trainees and tutorial programs to existing certification requirements, the Department of Health, Education, and Welfare should accept responsibility for bridging this gap between available personnel and manpower need. One means for executing that responsibility is embodied in bills currently before Congress,[181] providing statutory authority for use of Veterans' Administration medical facilities in the training of professional and auxiliary health personnel. The Department should stand ready, on enactment of these provisions, to formulate and encourage supplementary training programs for partially trained personnel as well as for new recruits to the auxiliary medical occupations; to facilitate cooperation among professional and regional associations in the accreditation of such programs and certification of its successful candidates; and to advise the Congress on legislation necessary to the support of such activities, as is now provided for health occupations training in established institutions.

In certain other health occupations there exist no standards at all. For example, only 162 cities and towns out of a nationwide sample of 900 require attendants to accompany ambulance drivers. [182] Generally such services are provided by undertakers; and of the attandants provided by them, only about one-fourth are reported to have passed the American Red Cross advanced first-aid course and only half to have passed the standard first-aid course.[183] The President's Committee for Traffic Safety has stated that even the advanced course is inadequate for ambulance personnel who handle persons with serious injuries:[184]

> Yet, for the most part, we send out to the scenes of accident people who don't know a tourniquet from a squash racquet, much less how to move a person with an injured back or how to treat for shock—from which as many people die as from wounds. [185]

[180] Prof. Eli Ginsberg, "Manpower in a Service Economy," Training Health Service Workers: The Critical Challenge (proceedings of the Conference on Job Development and Training for Workers in Health Services, Washington, D.C. Feb. 15, 1966), p. 17.

[181] S. 2666, S. 2748, S. 3086, and H.R. 11631, 89th Cong., 2d sess., cf. hearing before the Subcommittee on Veterans' Affairs of the Committee on Labor and Public Welfare, U.S. Senate, 89th Cong., 2d sess., Mar. 23, 1966, p. 56.

[182] Dr. Francis Keppel, "National Responsibility for Health Manpower," in Training Health Service Workers: The Critical Challenge (proceedings of the Department of Labor—HEW Conference on Job Training for Workers in Health Services, Washington, D.C., Feb. 14, 1966), p. 13.

[183] Medical Tribune, Aug. 20–21, 1966, p. 12.

[184] Medical Tribune, Apr. 9–10, 1966, p. 12.

[185] Keppel, op. cit., n. 91.

In this and other health occupations where standards are lacking, it is important for the Department to initiate adequate remedy among the institutions and governmental authorities responsible.

Inherent in the many programs to recruit and train health manpower is the maintenance of adequate training standards. In the Department of Health, Education, and Welfare this is the concern of the Public Health Service, the Office of Education and the Vocational Rehabilitation Administration.

The Commissioner of Education has designated certain organizations as nationally recognized accrediting agencies and associations for higher education and for some health occupations schools. Standards for training in medical technology, for example, are established by the Council on Medical Education of the American Medical Association and recognized by the National Commission on Accrediting. Outside of this professional regulatory framework, however, exists a number of proprietary schools of questionable intent which appear to set their own standards and establish their own accrediting and certifying organizations. In contrast to the 4-year curriculum recognized by the AMA and the junior college programs recognized by the regional accrediting associations, these schools offer superficial 1-year programs in "medical technology" and supposedly in other health occupation categories. Their programs frequently are characterized by high fees, questionable business practices, high pressure salesmanship and substandard instruction, often by unqualified instructors.[186]

Graduates of these programs become "certified" through agencies founded and controlled by the proprietary schools themselves. Such certification is dependent more upon payment of fee than completion of an approved course. For example, 2 years ago one Straybourne Betts, a dog of mixed breed, was certified as a "medical technologist" by two of these private accrediting agencies. (Fig. 8). This year Mollie Bloom Connor, a 3-year-old Saint Bernard, was certified by another such agency as a "dental assistant." [187]

[186] Some of these practices were described in a series of articles by Alvin Remmenga in the Minneapolis Star, Feb. 15–17, 26, and Mar. 22, 1965; by Alice Lake in McCall's, May 1965; by James Ridgeway in The New Republic, February 1966; and in Modern Hospital, December 1961.

[187] James Ridgeway, "The Girls in White," The New Republic, February 1966.



FIGURE 8.—Straybourne Betts, of Glen Echo, Md., certified as a medical technologist by the International Registry of Independent Medical Technologists in Enid, Okla., and as medical laboratory technologist by the International Sociaty of Clinical Laboratory Technologists in St. Louis, Mo.

INTERNATIONAL REGISTRY
OF INDEPENDENT MEDICAL TECHNOLOGISTS,
Enid, Okla., January 15, 1963.

STRAYBOURNE BETTS, M.T.,
Glen Echo, Md.

DEAR MR. BETTS: This will acknowledge receipt of your application for membership in the International Registry of Independent Medical Technologists.

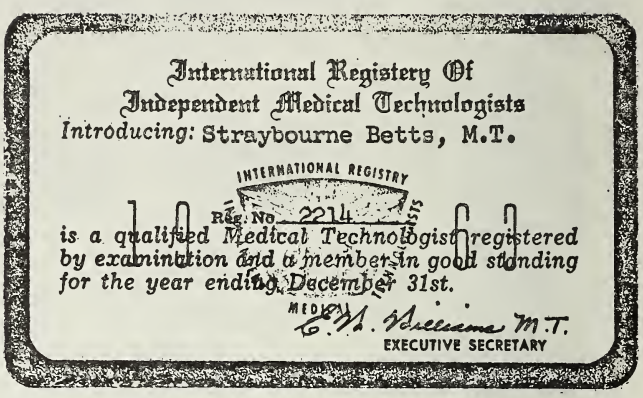
It is an extreme pleasure to have you join our ranks to stand up and be counted for the principles in which we believe. You can lend us a great deal of assistance by encouraging all of your friends to consider our registry. Our newspaper is at press and should be in the mail next week and we do want you to show it to your friends.

Enclosed is your identification card. Your certificate will be forwarded right after our next printing.

Sincerely yours,

E. W. WILLIAMS, Sc. D.,
Executive Secretary.

FIGURE 10

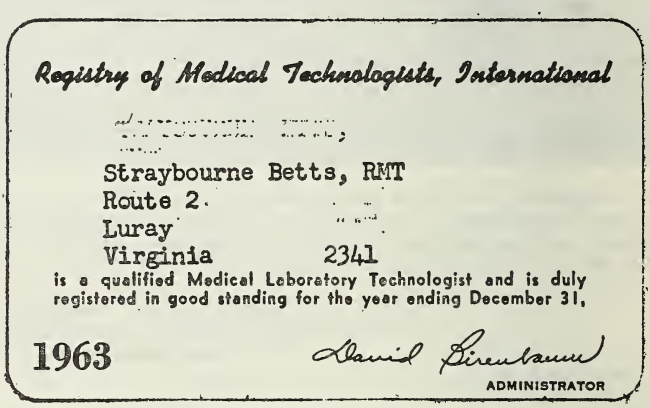


International Registery Of
Independent Medical Technologists
Introducing: Straybourne Betts, M.T.

INTERNATIONAL REGISTRY
Reg. No. 2214

is a qualified Medical Technologist registered by examination and a member in good standing for the year ending December 31st.

MEDICAL TECHNOLOGISTS
EXECUTIVE SECRETARY



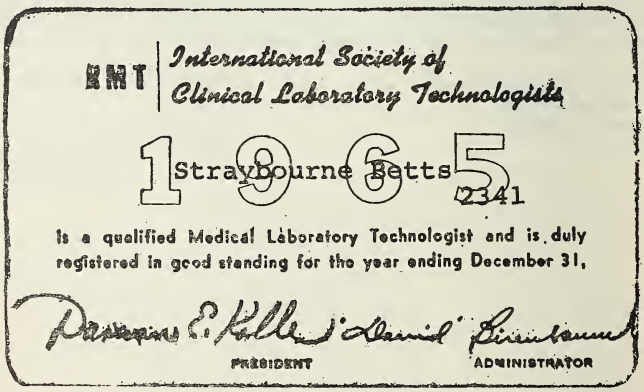
Registry of Medical Technologists, International

Straybourne Betts, RMT
Route 2
Luray
Virginia 2341

is a qualified Medical Laboratory Technologist and is duly registered in good standing for the year ending December 31,

1963

ADMINISTRATOR



RMT | *International Society of Clinical Laboratory Technologists*

1965

Straybourne Betts 2341

is a qualified Medical Laboratory Technologist and is duly registered in good standing for the year ending December 31,

PRESIDENT ADMINISTRATOR

The fact that these "schools" are sometimes "licensed" by State agencies is not in itself a protection, since often this requires no more than the payment of a license fee, or a permit for a salesman to sell courses to students of that State. Even when inspection is required, the licensing apparatus is sometimes very flexible in regard to Federal support requirements. For example, one school in North Carolina was last year refused a license by the State licensing agency for vocational and technical schools as substandard, yet has retained its approval for veterans benefits within the State.[188] (The school in question is among those "accredited" by one of the agencies that "certified" Straybourne Betts.) A similar school in Ohio, "approved" by another self-authorized "accrediting bureau" dissolved following litigation but has reopened with the same courses, as a "junior college." [189]

The consequences of inadequate or substandard training, especially in occupations such as medical technology where test results directly affect diagnosis and treatment, can be serious. The danger is particularly acute in rural areas, where manpower shortages are accentuated and laboratory supervision is minimal. A Minnesota Department of Health study a few years ago indicated that the majority of laboratories in rural hospitals, which accounted for three-fourths of all those in the State, were operating under the technical supervision of persons who were unable to qualify as medical technologists under AMA standards.[190]

The House Interstate and Foreign Commerce Committee has commented previously regarding our Nation's dependence on allied health workers in future provision of quality medical care.[191] In the health occupations, where standards of training directly affect patient care, the Department of Health, Education, and Welfare bears a responsibility in seeing that adequate standards are established and maintained; that adequate protection is afforded patients and students against unprofessional training practices; and that within these boundaries accreditation is kept flexible enough to accommodate new health occupations and new sources of training.

RECOMMENDATION E: THE PUBLIC HEALTH SERVICE SHOULD EXERCISE GREATER INITIATIVE IN DEVELOPING EFFICIENT METHODS OF HEALTH CARE DELIVERY AND MULTIPHASIC SCREENING

The recruitment, training, and utilization of new categories of health workers was advised in recommendation C. Prerequisite to this, strong support should be given to research in job analysis and motion study. Alleviation of manpower shortages depends not only on additional workers, but also on trimming tasks to essential functions, assigning those functions on the basis of ability required, and aligning those abilities with the tasks necessary for quality patient care. Medical procedures are still influenced by tradition. They have not been simplified or separated into associated components as have industrial procedures.

[188] Information furnished by the Institutional Status Unit, Bureau of Higher Education of the Office of Education, HEW. The confusion arising from operations of private accrediting associations has been the subject of statements issued by the National Commission of Accrediting.

[189] "There is no law [in Ohio] that prevents anyone from opening up any kind of school, calling it whatever he wishes, and passing out diplomas." Cleveland Press, June 13, 1966, p. B-6.

[190] Ruth Heinemann, Henry Bauer, and Helen Kundsen, "Design for the Development of Medical Laboratories," American Journal of Medical Technology, May-June 1959, pp. 164-165.

[191] H. Rept. No. 1628, 89th Cong., 2d sess., p. 5.

Similarly, full account has yet to be taken of the impact of automation on health care methods. Some hospitals have introduced direct ordering and prepackaging of pharmaceuticals, for rapid and efficient delivery by nurses. Certain coronary care units monitor patients electronically, for quicker control by fewer personnel. Computers assist in patient diagnosis, information flow, and management aspects of hospital operation. A Texas hospital applied computers to rehabilitation problems, resulting in significant reductions in long-term hospital stays as well as in improved methods of therapy.[192] As a result of an automation manpower services demonstration in a St. Paul hospital, "a chronic shortage of trained nursing personnel was reduced * * * [and] at the same time, the quality of patient care was improved".[193] Many other technological innovations are within current possibility. But they are introduced sporadically where they are introduced at all. There is no planning underway for massive technological change in medical services, no assessment of its total impact, no estimates of manpower savings, no design studies that would interrelate several types of automation for optimum utilization.

There is need for a central manpower records system or health "data bank" to match personnel with jobs, improve administration and provide the basis for future manpower planning, management and research. The Association of American Medical Colleges expects to put a model system in use by 1969. This effort has not been joined or matched in the Public Health Service.

Advanced delivery methods have been in operation throughout many European countries for some time, with beneficial results both for patient care and for manpower problems. But the Public Health Service is not engaged in any systematic study of such methods for the extrapolation of solutions applicable to similar problems in American medicine.

The same kind of technology that makes miracle cures possible also makes them in many instances avoidable. There are tests for cervical cancer, for phenylketonuria, for "lazy-eye" defects that have led to 1 million cases of blindness, and for many other diseases. There are autoanalyzers and other types of machinery to process tests quickly and accurately. There are X-ray, EKG and other diagnostic machines small enough to completely outfit mobile diagnostic facilities. But they do not reach the people who need them most, and often neither do the vaccines that prevent diseases from happening. Other measures that forestall disease, such as health education and the promotion of proper nutrition, have not yet been made appealing to vast sections of the American public.

Similarly, there has been very little effort made to promote multiphasic screening as a form of preventive medicine. When linked to a systematic procedure and assisted by computers, diagnostic tests can be made self-auditing, capable of assigning an array of secondary checks upon positive indication from a standard test. With proper followup it will lead to discovery of unknown conditions before they become acute, and will assist in the management of known but neglected conditions. When administered to a population it can help mitigate or avoid serious disease, its cost, and the manpower necessary to treat it.

[192] "Psychiatrist Clicks With Computers," Medical World News, Oct. 29, 1965, p. 130.
[193] Dennis Sohlstrom and Russell Sudeith, "Technological Change in a Hospital," Employment Service Review, May 1965.

Fifteen years ago the International Longshoremen's & Warehousemen's Union is San Francisco arranged through the Permanente Health Plan for multiphasic screening of 4,000 union members. Under a battery of only 12 diagnostic tests, two-thirds of these men showed positive results and one-fifth of them were reported with previously unknown conditions—including malignant neoplasms, pulmonary tuberculosis, syphilis, diabetes, hearing and sight impairments, cardiovascular disease, nephritis, nervous disorder and respiratory conditions.[194] The total cost of screening and followup (exclusive of therapeutic management) averaged $9.13 per person tested. Several additional benefits flowed from this multiphasic operation: health education among workers formerly suspicious of examination, correlations between socioeconomic status and disease incidence, and the inclusion of multiphasic screening services as a regular feature of the Kaiser-Permanente Health Plan.[195]

Test batteries and screening procedures have improved considerably since the longshoremen's demonstration. It is now possible to screen 24,000 persons per year in a single multiphasic clinic. All of the equipment required will fit into a small neighborhood apartment or into a mobile unit for rural areas. The testing may be performed by nurses and medical technologists and fed into magnetic tapes for computer analysis and automatic auditing. The per patient cost for testing large populations is still very low.

Our attention to maximizing health manpower utilization demands consideration of eventual periodic multiphasic screening for every citizen of the United States.[196] It is unsuitable that the "medical checks" administered to much of the population be only those designed by employers primarily for the purpose of refusing employment to the impaired. Multiphasic screening facilities might be combined with low cost referral diagnostic services, similar to those provided by the "doctor's laboratories" in Denmark, which are manned by biotechnicians trained in testing procedures to furnish, efficiently and on short notice, local physicians with diagnostic information.

RECOMMENDATION F: THE QUALITY OF HEALTH SERVICES DELIVERED TO THE PUBLIC AND ITS RELATIONSHIP TO EFFICIENT MANPOWER UTILIZATION SHOULD BE A MAJOR CONSIDERATION IN RESEARCH AND DEMONSTRATION MISSIONS OF THE PUBLIC HEALTH SERVICE

Four years ago the six hospitals of Rochester, N.Y., organized a fundraising campaign for additional hospital accommodations. But instead its chairman, a former Secretary of Health, Education, and Welfare, converted the effort into a patient care planning council for the purpose of conducting studies on hospital utilization. The council found that (1) 30 percent of their acute bed patients could be better accommodated by less expensive types of medical services, such as outpatient and extended care services; (2) providing such services would obviate the necessity of much of the anticipated additional

[194] E. Richard Weinerman, Breslow, Belloc, Waybur, and Milmore, "Multiphasic Screening of Longshoremen With Organized Medical Followup," 42 American Journal of Public Health 1552 (December 1952).

[195] Goldie Krantz, "A Multiphasic Health Program—A Supplement to Health and Welfare Plans," 52 American Journal of Public Health 2087 (December 1962).

[196] The need for improved methods of screening groups of children is already well recognized in the Children's Bureau, but the need remains undeveloped. Cf. "Health of Children of School Age," Children's Bureau Publication No. 427-1964, p. 17.

hospital facilities and skilled personnel; and (3) certain hospital services, such as laundry, could be centralized for further savings.[197] Three years later the State of New York adopted a statewide policy of medical review procedures, on the recommendation of the Governor's committee chaired by the same former Secretary.[198]

Recent studies by a medical audit unit in New York City reviewing medical care facilities available to members of a hospital insurance plan revealed that 43 percent of the care delivered was performed in a "less than optimal" fashion; i.e., there was "failure to explore fully the symptoms for which the patient had been hospitalized and to establish a diagnosis for which a rational treatment program could be instituted." [199] Incidence of "less than optimal care" was highest "in all hospitals other than those affiliated with medical schools." Furthermore, it was found that competence of attending physicians depended more on the quality of their working environment than on their training. As a result the Commissioner of Hospitals instituted a system of "affiliation" between municipal and medical school hospitals to rationalize manpower and increase the quality of care in the most deficient units. The Commissioner's subsequent opinion was that—

> It is a safe assumption that no one lives or works in an area where the quality of medical care does not need improvement in some way. * * * [T]he public again needs public health leadership in improving medical care.[200]

Quality of care is the key to effective utilization of manpower. Although the studies that are available indicate considerable urgency in these matters, there is at present no concentrated effort in the Public Health Service designed to insure high standards of medical care of all Americans. In the subcommittee's view, improvement in quality of medical care should be a primary objective of the Public Health Service in the years ahead and should receive greater emphasis in its research and demonstration programs (see also recommendation I, Part A, of this report).

[197] Marion B. Folsom, "Today's Health Needs and Tomorrow's Services," 53 American Journal of Public Health 863 (June 1963).

[198] Report of the Governor's Committee on Hospital Costs, State of New York, Dec. 15, 1965.

[199] "A Study of the Quality of Hospital Care Secured by a Sample of Teamster Family Members in New York City," Columbia University School of Public Health and Administrative Medicine, 1964, pp. 8, 18.

[200] Ray E. Trussell, "The Quality of Medical Care as a Challenge to Public Health," 55 American Journal of Public Health 174–175 (February 1965).

PART C—NATIONAL INSTITUTES OF HEALTH RESEARCH ACTIVITIES

Part C.—National Institutes of Health Research Activities

I. INTRODUCTION

Federal support of NIH activities has experienced a phenomenal growth in the past 15 years. The current budget of $1.2 billion (fiscal year 1966) is 23 times the size of the $52 million NIH budget in 1950. Furthermore the NIH budget represents more than half the $2.2 billion current budget for the entire Public Health Service.

In view of the phenomenal growth in the size and scope of the NIH activities, the subcommittee made a careful review of the overall NIH operation to determine whether the NIH has developed adequate planning and administrative procedures to cope with the problems related to such growth, so as to enable it to carry out effectively and efficiently the many varied programs which it now administers. The subcommittee found much to commend the operations of the NIH and believes that generally there are continuing, conscientious efforts to support good research and good researchers. Moreover, it was shown that over the past years there have been considerable accomplishments resulting from these efforts. The subcommittee focused particular attention on (*a*) the adequacy of planning for the NIH extramural and intramural research programs and (*b*) the effectiveness of NIH administrative implementation of the Research Career Program, research grants to foreign institutions, and fiscal controls for extramural research grants. As a result of the subcommittee's study serious deficiencies were noted, both in the NIH capacity for planning and in its program administration. The subcommittee therefore recommends (1) that the NIH strengthen its capacity for long-range planning for determining optimum utilization of its funds and (2) that the NIH institute necessary reforms to tighten its administrative procedures for program implementation. The subcommittee's findings and recommendations are set forth in greater detail below.

II. HISTORY AND GROWTH OF NIH

In order to appreciate the types of problems now facing NIH, it is necessary to understand the history and growth of NIH, the changed emphasis of its primary research mission and the tremendous expansion in the types of "research" activity supported.

From its inception until the 1930's Public Health Service medical research efforts were directed toward infectious illnesses. However, as the danger posed by these illnesses subsided, a new research policy was inaugurated which was directed toward the chronic diseases—especially cancer and heart disease. This policy was manifested by the creation of the National Institute of Health in 1930 (the name was pluralized in 1948) which became both a means of emphasizing the chronic diseases and a vehicle for the expansion of federally sponsored medical research. The National Institute of Health was established "for the special purpose of pure scientific research to ascertain the

cause, prevention and cure of diseases affecting human beings." [201] Accordingly, at this time research emphasis was placed on objectives which were for basic studies designed to obtain "fundamental knowledge concerning the chemical conditions which control the life, growth, and multiplication" of normal and abnormal cells.[202] This emphasis on basic research paralleled the increasing emphasis on chronic diseases. Appropriations under authorization of title VI of the Social Security Act between fiscal year 1936 and 1940 allowed significant expansion of federally sponsored medical research and indirectly produced a new concentration on the chronic diseases. The Surgeon General stated in 1937 that "the acute infectious diseases have declined rapidly under the impact of public health effort." But there had been a concomitant increase in many of the diseases of adult life, particularly the chronic diseases. He further stated that public health services should shift emphasis to the prevention and treatment of the chronic diseases.[203]

The NIH research program originally was intended to be only an intramural research program. Thus the Senate report accompanying the act establishing the National Institute of Health stated:

> The plan of the Institute is to make of it a great cooperative science organization in which leading experts in every branch of science will be brought together and given opportunity to work in unison for the purpose of discovering all the natural laws governing human life, and especially to learn those variations of such laws which are detrimental to human health. It is confidently believed that if there is brought together in one central plan under one directing head the very ablest experts in the sciences of medicine, surgery, chemistry, physics, biology, bacteriology, pharmacology, pharmacy, dentistry, etc., and a concentrated, united effort for term of years is made by them against disease, singling out first the more important maladies such as cancer, tuberculosis, common cold, pneumonia, etc., that success will result therefrom.[204]

During World War II, however, a large extramural cancer research program was operated by awarding research contracts to universities, medical schools, and independent laboratories. The program functioned smoothly and produced good results. As a result of this experience, NIH urged that "governmental funds for research should be available for grants-in-aid to scientific institutions to ensure continuity of research and to enlist cooperation in investigations requiring a variety of professional skills." [205] The desired authority to award grants-in-aid in support of general medical research was granted by the passage in 1944 of the Public Health Service Act, section 301 of which empowered the Surgeon General to "make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals" in carrying out the general purpose of conducting research "relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." However, it was not until December 1945 that PHS obtained approval from the Bureau of the Budget for sufficient funds for a general extramural research program by the transfer to Public Health jurisdiction of 44 wartime research contracts in order to insure their continuance. This provided the impetus for the large extramural grants program now administered by NIH. By December 1947 PHS had awarded 1,115 grants for a total of $11.5 million, and it began establishing study sections to give technical advice and to

[201] S. Rept. No. 1280, 70th Cong., 1st sess., p. 2.
[202] Annual Report of the Surgeon General of the Public Health Service of the United States, 1933, p. 7.
[203] Id., 1937, p. 14.
[204] S. Rept. No. 102, 71st Cong., 2d sess.
[205] Annual Report of Federal Security Agency, U.S. Public Health Service (1942–1943), p. XII.

review grant applications. In that year the Surgeon General also predicted that:

> New programs should emerge from the blueprint stage and all peacetime health services promise to gather increased momentum. As the country's health workers speed their attack on vital problems, particularly those related to chronic disease or old age, wide public support may be anticipated. Never before has there been such keen and widespread interest in health matters throughout the land.[206]

This anticipated expansion came about with the establishment of six additional disease-oriented institutes in the following 3 years, as shown by the following table, so that by 1950 there were seven such institutes.

Institute of Division	*Date of origin*
National Cancer Institute	1937
Division of Research Grants	1947
National Heart Institute	1948
National Microbiological Institute [1]	1948
Experimental Biology and Medicine Institute [2]	1948
National Institute of Dental Research	1948
National Institute of Mental Health	1949
National Institute of Neurological Diseases and Blindness	1950
National Institute of Arthritis and Metabolic Diseases	1950
Division of Biologics Standards	1955
Division of Research Services	1955
Division of General Medical Services [3]	1958
Division of Research Facilities and Resources	1962
National Institute of Child Health and Human Development	1963

[1] Changed in 1955 to National Institute of Allergy and Infectious Diseases.
[2] Absorbed in 1950 by National Institute of Arthritis and Metabolic Diseases.
[3] Changed in 1963 to National Institute of General Medical Sciences.

Source: PHS Publication No. 81.

Most of the NIH growth has taken place in the activities supported outside of the Institutes, i.e., extramural programs. Obligations for the extramural research programs increased from $15 million in 1950 to $893 million in 1965, whereas obligations for the intramural research programs only increased from $13 million to $82 million during this period. Research project grants constitute the largest category (52 percent) of NIH's extramural programs. These grants are made for the support of specific research projects initiated and proposed by individual scientific investigators.

As shown in the following table, research project grants have had the fastest rate of growth.

[206] Id. (1947), p. 269.

NIH grants and awards

[Dollar amounts in thousands]

Fiscal year	Total amount [1]	Research project grants		Construction grants		Research training grants		Fellowship and traineeship grants		Research contracts	
		Number	Dollars	Number	Dollars	Number	Dollars	Number	Dollars	Number	Dollars
1955	$55,200	3,280	$35,800	------	--------	557	$10,300	1,384	$3,700	------	--------
1956	64,700	3,475	40,400	------	--------	699	13,500	1,817	4,400	------	--------
1957	156,100	6,300	82,900	109	$30,000	1,119	25,600	2,566	7,300	43	$1,900
1958	191,300	7,134	101,300	177	30,200	1,367	31,900	2,743	8,500	176	11,000
1959	260,200	9,056	141,400	205	31,600	1,934	48,900	3,317	12,700	321	17,200
1960	354,700	11,571	198,800	171	30,800	2,626	73,700	4,255	17,900	286	23,100
1961	481,000	13,534	272,900	156	38,000	3,586	108,400	4,478	24,300	311	22,900
1962	600,300	14,975	372,100	112	36,800	3,697	115,900	4,010	29,600	419	28,100
1963	710,100	15,973	430,900	178	51,300	4,114	140,600	4,561	38,000	496	38,300
1964	815,900	16,017	497,900	129	53,900	4,346	165,900	4,872	44,500	597	42,700
1965	892,800	15,792	538,800	120	64,900	4,568	183,900	5,307	49,800	474	48,600

[1] Includes State control programs and community demonstration projects.

Source: Office of Program Planning and the Division of Research Grants, NIH.

During fiscal year 1965, the median award for research project grants was $20,330. Five awards amounted to over $1 million each and 966 awards were less than $5,000 each. The following table shows the pattern of support for research project grants during fiscal year 1965 by indicating the number and amount of awards by Institute or Division.

NIH research grant awards by granting authority, fiscal year 1965 [1]

[Dollar amounts in thousands]

Institute or Division	Number	Amount
Total [2]	15,183	$538,800
Allergy and Infectious Diseases	1,358	35,900
Arthritis and Metabolic Diseases	2,808	71,900
Cancer	1,514	56,500
Child Health and Human Development	956	26,600
Dental Research	339	8,400
General Medical Sciences	1,892	51,600
Heart	2,288	78,400
Mental Health	1,846	69,200
Neurological Diseases and Blindness	1,674	50,800
Research Facilities and Resources	407	86,700
International Research	101	2,700

[1] Includes research projects and program projects and centers.
[2] Excludes scientific evaluation grants of $2,400,000.

Source: Office of Program Planning and the Division of Research Grants.

NIH has maintained since 1937, when the National Cancer Institute was established, that "health research" must be given complete freedom and that there is a continuing need to add to knowledge through basic research. As a consequence of this premise and the broad authority given NIH by Congress, most of the NIH budget is used for the support of basic research. Basic research is concerned primarily with the discovery of new facts about nature and the formulation, development, and verification of scientific principles. The National Science Foundation defined it as follows:

Basic research is that type of research which is directed toward increase of knowledge in science. It is research where the primary aim of the investigator

is a fuller knowledge or understanding of the subject under study rather than a practical application thereof.[207]

Basic research can also be defined as an effort to produce new knowledge without concern as to its immediate applicability, as contrasted to "applied research" or "development research," where the knowledge generated is intended to apply to meeting a practical need. On the other hand, "programed research" or "directed research" is a goal-oriented program, which because of its exploratory nature and uncertainty of its scientific base, needs close and continued association with biomedical research groups. That is, basic research knows no limits, but directed research ceases when a predetermined goal is accomplished. Basic research usually is supported by grants, whereas directed research normally (though not always) is carried out through contracts.

NIH has supported relatively little directed research. This type of research requires that the principal elements of the research effort be specifically identified and described in advance, the problem defined, and usually time-targets are established for predetermined goals. The cancer chemotherapy program is an example of this type of research. This program was commenced in 1955 at the request of Congress in order to speed the search for cancer drugs through research and development in the laboratory and clinic. It includes every phase of drug research from the acquisition and screening of candidate drugs to clinical trials of those materials and dissemination of information on results.

Findings and Recommendations

Recommendation A: The NIH should strengthen its capacity for long-range planning

The most glaring deficiency noted by the subcommittee with respect to the NIH operation is the lack of effective planning procedures. This is particularly true for both the extramural and intramural research programs.

In the course of its examination of the NIH activites, many NIH officials attempted earnestly to convince the subcommittee that the present NIH planning procedures and mechanisms are satisfactory. A number of scattered, rudimentary planning "units", and other groups within NIH that include "planning" among their functions, were cited as implementing the NIH planning function. The main thrust of the arguments appeared to be, however, that a strong, coordinated planning operation at NIH is not needed because planning is "built into the system", i.e., it is performed by the study sections and advisory councils in the course of reviewing research project grants for the extramural program, and by the staff of each institute in the selection for its intramural "program," of researchers with known interests in particular fields. The subcommittee was impressed with the earnestness of the arguments of the NIH officials, many of whom apparently are convinced that the present system is an adequate substitute for a strong, coordinated planning operation at the NIH. Nevertheless, the subcommittee believes that the present alleged "built-in" planning system is no longer adequate or effective to cope with the burgeoning NIH activities and that the NIH planning

[207] "Federal Funds for Science, VIII. The Federal Research and Development Budget, fiscal years 1958, 1959, and 1960.", p. 32.

capacity, which may have sufficed for a considerably smaller operation 10 to 15 years ago, now is in considerable need of strengthening. This need is made all the more paramount by the fact that the present "built-in" planning mechanism for NIH research programs has been revealed by the subcommittee's investigations to have many serious weaknesses, as will be discussed more fully below.

1. Extramural Research Program.

(*a*) *Review procedures for extramural research grants.*—The NIH review procedures in effect for extramural research grants are basically the same as when research grants were first authorized in 1944. Applications are submitted by scientific investigators, through their affiliated university or research center, to the NIH Division of Research Grants. This Division serves as the administrative coordinating center for the extramural programs and in this capacity arranges for the review of all research grant applications. The applications receive an initial review for technical qualifications ("scientific merit") and a subsequent review for "program relevance" by NIH external advisory groups.

External advisory groups (National Advisory Councils, study sections, or other initial review groups) are an integral part of the Public Health Service. As of October 1, 1965, 265 public advisory groups were used by Public Health Service, of which 206 were used by the National Institutes of Health. (See app. G, pts. 1 and 2.)

The technical review of grant applications is performed by study sections or other initial review groups which are organized on the basis of scientific disciplines and medical specialties. These initial review groups are established administratively by the Surgeon General. A copy of each grant application also is forwarded by the Division of Research Grants to one of the various Institutes and Divisions of NIH for consideration by its staff and for subsequent "review" by the external Advisory Council for that Institute or Division after the initial review by the study section. The Advisory Councils were created by the Congress to advise the Surgeon General with respect to individual project applications and the formulation of research and training policies. Section 301 of the Public Health Service Act provides that the Surgeon General may not award a grant that has not been recommended by the Advisory Council. The processing of a grant application usually requires approximately 6 to 8 months.

This system of review and approval is considered desirable by PHS and the scientific community primarily because the applications are independently judged by peers, and not Government authority. Furthermore, under this system NIH cannot be accused of prejudicial action because grant approval is dependent upon a recommendation of a Council, and the Councils are not subject to criticism because they are not responsible for administering the NIH program. However, one of the major weaknesses of this system now, in the opinion of the subcommittee, results from the fact that it was devised for a much smaller volume of grant applications than are presently being processed, and it is virtually impossible for the initial review group and/or the Council to conduct completely satisfactory reviews in the limited time available. Although the number of study sections and other advisory groups admittedly has increased, this increase has not been in proportion to the increase in the number of grant applications.

Moreover, there has been an explosion of scientific knowledge resulting from the emphasis placed on research. An essential element of the grant approval system is based on the assumption that the combined knowledge of the members of study sections and councils will, in each case, include all of the latest information available in their particular specialty. Such an assumption appears to be patently unrealistic.

(*b*) *Study sections.*—As of October 1, 1965, there were 51 study sections. A study section consists typically of 13 to 15 scientists chosen for their knowledge of a particular field of service. Study section members total more than 600. The scientists serving on the study sections are appointed for 4-year terms and cannot serve consecutive terms on the same study section. They are drawn mainly from universities, although hospitals, research institutions, and agencies of the Federal Government are also represented. Members of the NIH intramural research staff may also be appointed to serve on these initial review bodies.

The function of the study sections is to make an evaluation as to the scientific merit of a research proposal. Among the factors taken into consideration are scientific significance, the design of the proposed research, the competence of the investigator or investigators to carry out the proposed work, the scientific and administrative environment, the adequacy of resources and facilities, the relationship of budgetary estimates to the proposed work, the feasibility of the plans and the overall significance of the project in relation to the need for knowledge in the scientific areas involved. Study sections usually meet for 3-day sessions three times a year. Subcommittee staff members attended a number of these meetings and generally were impressed with the efficient manner in which they were conducted and the conscientiousness of the individual members.

Before each meeting, each member is given responsibility for examining with special care, and summarizing for his colleagues, a group of applications which fall within his special field of competence. One study section member is given primary responsibility and another member secondary responsibility for a particular grant application; they normally have 30 days to examine the application prior to the study section meeting. Considering the number of grant applications usually assigned to a study section, the full panel has an average of a little more than 10 minutes during the meeting to discuss and evaluate each application. The subcommittee was informed that this is considered adequate deliberation. However, considering the short time available for discussion, and the record which shows that the members of the full study section usually tend to agree with the recommendation of the one member responsible for the primary review, the recommendation for approval or disapproval of the grant application by the study section appears generally to be the judgment of one peer.

NIH officials insist that there is considerable "scientific honesty" in the deliberations of the study section members, who are dedicated to accuracy and competence. They informed the subcommittee that "their dedication to the advancement of science is such that these men cannot tolerate anything but the highest grade of work." NIH officials stated that the scientists serving on the panels do not hesitate to criticize any aspect of a proposed research grant which appears to be in any way unsound or to reject such proposals. This contention

is borne out by the fact that the rate of application disapprovals is quite high. In some Institutes it is as high as 50 percent. Moreover, an NIH statistical study showed that scientists are not prejudiced in favor of grants for research at their own institution or by a colleague. In fact, the study showed that institutions had a lower rate of research grant approvals when members of the institution were serving on study sections and advisory councils than when they were not.[208]

Nevertheless, the fact that there is considerable scientific honesty in the study sections does not negate the fact that the study sections are overtaxed to the point that an effective evaluation of grant applications cannot be reasonably expected. It would appear that consideration should be given to revising the system for review and approval of grant applications in order to better cope with the present large volume and high degree of complexity of the applications.

In addition to reviewing research applications in their respective fields and forwarding their recommendations to the appropriate National Advisory Council, one of the stated responsibilities of each study section is "to survey, as scientific leaders, the status of research activities in their fields in order to determine and recommend to the Public Health Service areas in which research and training activities should be initiated, expanded, or curtailed." [209] A few instances were p inted out to the subcommittee in which a particular study section had recommended that a workshop discussion be held to discuss, and hopefully generate applications in, a particular area of research. However, it was apparent from the subcommittee's review that this is by no means a regular activity of the study sections which, as indicated above, are hard pressed to give adequate consideration to the research applications assigned to them for review.

In February 1965, a report was issued by the Wooldridge Committee which had been formed in 1964, at the President's request, to conduct a qualitative evaluation of the NIH operations in order to provide assurance that it was being conducted with maximum effectiveness. The Committee consisted of 11 panels; each panel issued a separate report, in addition to the overall committee report. With regard to the study section operations, the Behavioral Science Panel reported:

> Although the study section mechanism is highly valued, we are unaware of any careful study of its operation other than a small one now being conducted by the NIMH Small Grants Study Committee. One would like to know the answers to such questions as: Does study section discussion modify a priority rating based only on reading the application prior to discussion? What determines which applications are selected for site visits? Does a site visit modify an original priority rating? In which direction? How is the quality of the study section decision evaluated?[210]

Apparently these questions are still unanswered.

(c) *Advisory councils.*—The first public advisory committee authorized for a specified kind of work was in the National Cancer Institute Act, enacted in 1937. Subsequently, an advisory council has been authorized for each Institute. The functions of the National

[208] Relationship of Study Section Recommendations for Approval and Disapproval of NIH Research Grant Applications by University Representation on Study Section of Review, 20 Leading Universities, Fiscal Year 1960. By Design and Analysis Section, Program Analysis and Statistical Branch, Office of Program Planning, NIH, December 1962.

[209] PHS—Public Advisory Groups: Authority, Structure, Functions. June 1, 1963, p. 52.

[210] Biomedical Science and Its Administration—A Study of the National Institutes of Health, February 1956, p. 140.

Advisory Councils authorized by the Public Health Service Act are described as:

> Reviews applications for grants-in-aid relating to research and training projects in the field of * * * [specific Institute] diseases and recommends to the Surgeon General the approval of those projects which merit support. Collects information as to studies being carried on in the United States and abroad relating to * * * [specific Institute] diseases and makes such information available to interested individuals and organizations. Makes recommendations to the Surgeon General with respect to the acceptance of conditional gifts pursuant to section 501 of the Public Health Service Act.[211]

The advisory councils are said to be primarily advisory in nature. The Department informed the subcommittee:

> From all its committees, the Service seeks constant advice and counsel on matters of program policy—new emphases, new directions, alternative methods * * * The public advisory committee is a device for interpreting a program to the interested public; it is a link with public opinion; it is an instrument of democratic administration.[212]

It was further stated that the work the advisory groups do for the Public Health Service could not be accomplished as effectively through normal staff channels. The Public Health Service indicated:

> As the actual roles of the Councils have evolved over the years the members have developed a sense of participation, responsibility, and involvement with Public Health Service programs which goes far beyond their literal, limited, statutory role. Their critical sense and high standards have been an indispensable part of the development of the Public Health Service grant and award programs. They have developed an effective easy, working relationship with the Institutes which they advise.[213]

Each advisory council is made up of 12 members appointed by the Surgeon General from among persons prominent in science and public affairs. Section 217 of the PHS Act specifies that—

> The twelve appointed members shall be leaders in the field of fundamental sciences, medical sciences, education, or public affairs, and six of such twelve shall be selected from leading medical or scientific authorities who are outstanding in the study, diagnosis, or treatment of the diseases to which the activities of the Institutes are directed * * *.

The summary statement of the grant application prepared by the study section indicating the recommendation for approval or disapproval as well as the scientific evaluation, is forwarded to the applicable National Advisory Council responsible for making an evaluation for "program relevance."

As in the case of the study sections, the councils usually meet in 3 day sessions three times a year, a few weeks after the corresponding study sections meet. The major portion of the councils' meetings is spent in taking action on grant applications. Summaries of study section evaluations are presented to members in advance of the meeting. The subcommittee was advised that councils do not attempt to evaluate the applications for scientific merit but rather for "program relevance." However, it was not clear to the subcommittee how this evaluation is made. The affirmation of study section actions is usually done in large blocks with a minimum of discussion. This is not to imply that most of the Council members may not attempt to make an evaluation based on the information furnished in advance and on

[211] "PHS—Public Advisory Groups: Authority, Structure, Functions," U.S. Department of Health, Education, and Welfare, June 1, 1963, pp. 24, 32, 34, 36, 37, 39, 40, 42, and 44.
[212] "Background Material Concerning the Mission and Organization of the Health Activities of the Department." U.S. Department of Health, Education, and Welfare, March 1966, p. 34.
[213] Public Health Service, Committee Management Handbook, July 1964, app. 28.

their own expertise. Rather, the evaluation was not apparent from established procedures or criteria. The sheer volume of the grant applications to be considered makes it impossible to have lengthy individual evaluations.

The study sections assign priority ratings to each application they approve, to serve as guidelines to the Council and the Surgeon General in determining which of the applications merit preference, since funds will not necessarily be available to pay all of the approved applications. The priorities are assigned by the study section within a discipline without regard to the Institute that will be responsible for the grant. Since funds are not equally available at each Institute, a grant application with a certain priority rating may be funded by one Institute, whereas another grant application within the discipline with the same or higher priority rating may not be funded by another Institute due to the unavailability of funds.

The councils are aware that all approved applications may not be awarded due to limitation of funds. However, as shown in appendix G, part 4, awards were not made uniformly in accordance with the assigned priorities, i.e., a number of low priority applications were awarded whereas a number of high priority applications were not awarded. The subcommittee staff was informed that this situation was the result of the various Institutes removing a number of high priority applications because of some development subsequent to the Council approval. Although the reasons for withdrawing high priority applications may have been valid, it is significant to note that the Councils are not informed of such withdrawals. In fact, the Councils are not systematically informed as to which applications approved by them were actually awarded and which were not.

It should also be noted, as shown in appendix G, part 4, that the actions taken by the Councils are largely an affirmation of the actions taken by the study sections. Using the National Heart Institute as an example, of the 730 applications approved by the Council, 705 were in amounts equal to the amounts approved by the study section; the Council approved only one application (amounting to $17,000) that had been disapproved by the study section and disapproved 13 applications (requesting a total of $257,000—an average of less than $20,000 each) which had been approved by the study section.

It has been contended that the Advisory Councils are a "rubber stamp" operation, since evidence points to the fact that very little independent action is taken on research applications. NIH officials hasten to deny this criticism of the Advisory Councils, contending that the Councils provide inavaluable advice and counsel to the Institutes in particular and the scientific community in general. With respect to program planning, NIH officials pointed out that although there is no separate item for program planning on the agenda for Council meetings, during the course of evaluating and discussing particular grant applications the Council expresses itself on the desirability of research in various areas—not just the one being discussed. However, this does not appear to be an effective or systematic approach to an important and complicated problem. As in the case of the study sections, the review procedures by the Councils were devised when the volume and complexity of applications were considerably less, and it now appears questionable whether the Coun-

cil review is of much value. As stated above, it is not clear how the Council's review for "program relevance" is made; moreover, it is not clear how it can be made when the Council members are not aware of any specific overall program. The subcommittee believes that the Councils would be of greater service if more time were devoted to reviewing and recommending a specific overall program for the individual Institutes and Divisions of NIH which they are advising.

Certain members of the scientific community also question the value of the Councils as presently operated. For example, a recent member of the National Mental Health Advisory Council informed the subcommittee:

> I do not think that the Advisory Council on which I sat justified the time and effort that it took from busy people. We were largely a rubber stamping operation, second guessing the study groups. I am sure that we helped the Director from time to time by providing him a sounding board; and we may even have taught the staff something now and again. But the staff wanted to run its show, its way—together with the study groups. The Council was something that it had to tolerate * * *. I am by no means sure that any "outside" group can ever be truly effective—surely not without its own staff. But we had a low order of effectiveness. To hammer the point home—I would not serve again.

Although the Ruina Committee, formed in December 1965 to review some of the administrative arrangements and management controls of NIH's grants and contracting programs, did not believe that the dependence on peer groups for preliminary screening of grant applications resulted in a mere "rubber stamp" function for the Advisory Councils, it had the following criticism of the Councils:

> The review and evaluation of each program, and of groups of related programs, appears to be imperfectly accomplished at NIH. Here is a place where efficient and candid communication between internal managers and external advisory bodies is vitally necessary. The advisers should be enabled by the responsible managers to get a true, comprehensive picture of the program they are helping to evaluate, uncluttered by superfluous details and yet subject occasionally to detailed scrutiny for audit purposes. Conversely, they should recognize that criticisms and suggestions relative to minor details are not effective substitutes for judgments relative to the broader aspects of the total programs. In the major program evaluations which each Institute must make from time to time, the Advisory Council is clearly designated by statute to participate. It appears that the Institutes have not been uniformly successful in utilizing their respective Councils in these evaluations. It is not surprising to us that a Council finding itself unable to get a comprehensive picture of a major program from the information presented to it, would seek (though mistakenly, in our opinion) to relieve its uneasiness by involving itself, instead in the details of management. * * *[214]

2. Intramural programs

All of the Institutes, except the National Institute of General Medical Sciences, conduct "intramural programs"—that is, research conducted by its own experts carried out primarily in PHS laboratories. As previously stated, the obligations for the intramural research programs increased from $13 to $82 million between 1950 and 1965. Although this increase is impressive, the rate of increase is not as large as that of the extramural program. Whereas in 1950 the intramural program and extramural program were approximately equal, in 1965 the total extramural program was more than 10 times as large as the intramural program.

[214] Report of the Secretary's Advisory Committee on the Management of NIH Research Contracts and Grants, U.S. Department of Health, Education, and Welfare, March 1966, p. 14.

The following table indicates the relative size of the intramural research programs by Institute for fiscal year 1966:

NIH estimated obligations for intramural research for fiscal year 1966

[000 omitted]

Institute	*Amount*
Allergy and Infectious Diseases	$12, 620
Arthritis and Metabolic Diseases	12, 814
Cancer	17, 376
Child Health and Human Development	2, 809
Dental Research	4, 070
Heart	11, 426
Mental Health	12, 149
Neurological Diseases and Blindness	8, 841
General Medical Sciences	-------
Total	82, 105

Source: Office of Program Planning and the Division of Research Grants.

The types of research projects undertaken in the intramural program do not differ greatly from those supported by the extramural program. The Director of NIH informed the subcommittee that he considers the intramural projects to be essentially an enlargement and extension of the extramural program. The Wooldridge Committee reported:

> More than half of the 10,000 employees of NIH are primarily occupied with the conduct or support of health research projects that are essentially indistinguishable from those performed in universities under the extramural program.[215]

Most of the intramural projects are conducted by individual investigators or small groups of investigators. The method of approving projects is different than for the extramural program in that the projects, conceived by the individual investigators, are approved by the Institutes without the aid of an outside review group. However, each Institute has a Board of Scientific Counselors, which convenes twice a year. The functions of the Boards, established administratively, are described as:

> To provide advice to the * * * [specific Institute] on matters of general policy, particularly from a long-range viewpoint, as they relate to the intramural research program.[216]

The investigator in the intramural program is not required to partake in any of the management functions or other activities of NIH, whereas an investigator supported under the extramural program is usually required to do a certain amount of teaching and accept department administrative assignments. Moreover, the intramural program investigator is not compelled to continually publish reports on the interim or partial results from a long-range project in order to gain approval for continuing the project.

The Wooldridge Committee stated that the quality of the intramural research was excellent. However, it also expressed the following concern:

> * * * we believe that the emphasis in the intramural program should be on the types of work that are uniquely suited to performance in Federal facilities, rather

[215] Biomedical Science and Its Administration—A Study of the National Institutes of Health, February 1965, p. 35.

[216] "PHS—Public Advisory Groups: Authority, Structure, Functions," U.S. Department of Health, Education, and Welfare, June 1, 1963, pp. 25, 33, 35, 38, 41, 43, 45, and 46.

than simply to the conduct of university-type research. We have found little evidence that the current emphasis is of this nature.[217]

The subcommittee agrees with the general premise that the Government should not undertake a program that can readily be performed by non-Government establishments. If the intramural program were merely an enlargement and extension of the extramural program, as contended by NIH, the concern expressed by the Wooldridge Committee might have some validity. The subcommittee's review however, did not disclose how the intramural and extramural programs are coordinated so as to complement each other and so that one can be considered an extension of the other. The subcommittee believes that this could only be accomplished by an overall, coordinated planning procedure, which, as noted earlier, does not exist at the NIH. The Advisory Councils have no responsibility for the intramural program, nor are they systematically informed of the activities of the intramural program. The subcommittee believes that NIH should devise a system to coordinate the two programs whereby preestablished overall goals could be pursued by complementary projects, without overlap or interference in the realm of the two entities. Also, since the Advisory Councils are considered to be of value in advising the Surgeon General with regard to the extramural program, the subcommittee believes that the Councils should be utilized by giving them similar responsibility for the intramural program. If the Advisory Councils concern themselves with program planning as suggested previously, such planning should encompass the intramural program if it is intended to supplement the extramural program.

3. Long-range planning

The major finding and recommendation of the Wooldridge Committee, was that:

> The most important organizational need of NIH is the strengthening of its capacity for long-range planning, for determining the optimum utilization of its funds, and for insuring that its activities and policies have the continued understanding and approval of scientific and lay public. To help accomplish this strengthening, the committee recommends the establishment of a new advisory group [Policy and Planning Council] to operate at the level of the Director of the National Institutes of Health.[218]

The subcommittee's investigation confirmed the deficiency in NIH planning noted by the Wooldridge Committee. Moreover, the recommendation of the Wooldridge Committee for establishment of a Policy and Planning Council at the NIH Director's level still has not been fully implemented,[219] although such a council would appear to be a desirable step to help alleviate this deficiency.

Even more important, however, is the question of whether such a top-level council can provide the entire solution to NIH's planning needs, since the inadequacy in NIH planning exists not only at the Director's level, but also, as has been demonstrated, at all other stages of the NIH operation. Thus, as has been pointed out above, (a) the initial review groups have no time to do any significant planning, although the responsibility "to survey, as scientific leaders, the

[217] Biomedical Science and Its Administration—A Study of the National Institutes of Health, February 1965, pp. 36–37.
[218] Id, p. 1.
[219] See app. G, pt. 5.

status of research activities in their fields in order to determine and recommend * * * areas in which research and training activities should be initiated, expanded or curtailed" is one of their stated assignments,[220] (b) the Advisory Councils have no systematic planning activity, and their review of grant applications for "program relevance" appears to be of questionable value, (c) the Institutes themselves have only limited, rudimentary planning groups and (d) there is limited, if any, communication between the advisory groups for the intramural and extramural programs and little apparent coordination by the Institutes of the two programs.

The lack of any integrated, systematic approach to planning at the NIH appears to stem largely from the fact that two polarized attitudes have long prevailed regarding the proper mission of the NIH.

One view is that the NIH mission is to support basic research investigation of life processes, and any type of direction or establishment of targets would constitute an unwarranted interference with the traditional academic freedom of the scientist.

The other concept is that the NIH mission is to support research directed toward the prevention and cure of specific diseases and that plans toward this end should be made whereby program goals would be established and the bulk of the projects approved would be those related to these goals.

The Director of NIH explained this polarization as follows in a memo to the Institute Directors and Division Chiefs dated April 16, 1965:

> While much has been done and significant changes in both attitudes and operating practice have taken place, there remains a basic ambivalence concerning the scope and role of such functions in the conduct of scientific programs. In large part this ambivalence arises from a tendency for views of the planning process to assume an unnecessary and distracting polarity. One pole is the view that the concept of planning and its related activities involves the administration of science programs on a teleological principle with all parts bearing a purposeful relationship and resulting from deliberate and prior determinations. The other pole is the view that planning is an anathema in anything to do with science; that the most progress emerges from an unstructured setting in which serendipity is fostered by basing administration on the principle of laissez-faire and with a minimum of deliberate acts and processes. While neither point of view is wholly tenable, much less a basis of action, their presence suggests the current stage of development of these functions and the rate at which further evolution can take place.

These two polarized attitudes have been manifested in what appears to be polarized approaches by NIH in the type of projects now being supported i.e., (a) traditional basic research projects and (b) more recently, fully directed research projects, such as the Cancer Institute's cancer chemotherapy program and the Heart Institutes's artificial heart program. After almost two decades of supporting an ever-increasing amount of basic research, there appears to be a growing desire for more directed research so that the results of the basic research can more speedily be brought to a direct and tangible benefit in combating chronic diseases. More important, there is a growing impatience by the public for practical results from the extensive basic research. The need for extensive basic research has been justified through the years on the theory that there was an insufficient base of knowledge in research which had to be created and continually renewed. The present Surgeon General stated that "the support of the individual

[220] See footnote 209, ante.

scientist is the foundation of our biomedical research effort. The project grant system that has been developed to foster this support protects the scientific freedom and stimulates the creative initiative upon which all else depends." [221]

The subcommittee fully concurs in the need for the NIH to continue to support both basic research projects and directed research projects. It is apparent, however, that the new emphasis on directed research projects will make it increasingly difficult for the NIH to arrive at a proper balance in its support of these two types of projects. This places an increased premium on effective long-range planning by the NIH to achieve such a proper balance. As stated by the Surgeon General, "what is needed is a balance that encourages the growth of the creative core of biomedical research and still is responsible to the pressures for hot pursuit of the most promising leads." [222]

One of the major difficulties in any discussion of "planning" as it relates to scientific research is coming to a uniform understanding of terms as they apply to the problem. For example, Harvey Brooks, dean, division of engineering and applied physics, Harvard University, informed the subcommittee:

> I believe that "planning" and "program balance," while desirable in principle, are dangerous terms. If by "planning" it is meant charting the substantive course of scientific research centrally, then I am against planning. If by planning it is meant the development of scientific resources and manpower, with the substance left primarily to the working scientists themselves, then I think planning is desirable, always provided it is not overly specific as to precise areas of specialization. Planning also implies the continuous scanning of the whole output of basic research to identify areas which have reached a stage where a focused effort might have a significant payoff for health.

It is in this latter, vital aspect of planning that the subcommittee found the NIH to be particularly deficient. There appears to be no regular procedure or method for such a continuous scanning and systematic evaluation of the results of biomedical research (or even that supported by the NIH) in order to identify those areas of research which appear to be the most promising and in which further research effort therefore would be appropriate. The subcommittee believes that this type of planning process is urgently needed at the NIH in order to correct the present aimless funding of extramural project grants and to enable the NIH to achieve more optimal utilization of its funds.

The question remains as to who should do this type of planning. Obviously it cannot be done for all fields of biomedical research by one group, such as the Policy and Planning Council recommended by the Wooldridge Committee. Furthermore it would appear desirable that it be done on a basis consistent with the NIH administrative and funding units, i.e., the Institutes and Divisions of NIH, so that the research areas identified as needing greater research emphasis would then be defined and serve as a basis for determining the "program relevance" of individual project grant applications.

Conceivably, such a planning function could be assigned to the existing Advisory Councils. However, it is difficult to visualize how these councils could take on such an additional time-consuming assignment and carry out both it and their other responsibilities effectively. Furthermore, it might be preferable to assign to the

[221] Address presented at Merck Sharp & Dohme symposium associated with dedication of new research facilities, auditorium of Columbia University's College of Physicians and Surgeons, New York, N.Y., May 26, 1966.
[222] IBid.

Advisory Councils instead, responsibility for reviewing suggested research areas developed by a separate planning group or groups for the purpose of determining, as a matter of policy, which ones will become official "research program areas" of the Institute or Division, for both intramural and extramural programs.

Thus a preferable solution might be to establish an advisory Research Planning Council for each Institute and Division of NIH, which would have as its sole assignment the responsibility for continuous scanning and review of relevant biomedical research so as to identify research areas which appear to merit greater support or a more targeted research effort. Such a planning effort should be carried out, of course, in close conjunction with the respective Institute or Division staffs, who would do much of the spadework of collecting information on research in progress, etc., prior to meeting periodically with the Research Planning Councils.

Once approved by the Institute, such areas of research emphasis should be communicated to the scientific community through official publications so as to serve as a stimulus for further research grant applications in these areas. Such applications would be processed through the normal NIH review channels, including review by the appropriate study sections for scientific merit.

By way of clarification, the subcommittee is not recommending that all NIH research grant applications should fall within specifically defined research areas in order to be funded. The thrust of the recommendation is that, in the view of the subcommittee, greater weight should be given to research applications which are relevant to specifically identifiable research programs and that such research programs should be sufficiently defined so as to (a) permit a meaningful determination of program relevance and (b) stimulate an increased number of research applications in those areas.

In summary, the subcommittee recommends that the NIH take immediate steps to strengthen its capacity for long-range planning by (a) maximum utilization as soon as possible of the Policy and Planning Council recommended by the Wooldridge Committee and (b) establishment of a planning process at NIH which will permit continuous scanning of all biomedical research to identify areas which merit greater support or which have reached a stage where a focused effort might have a significant payoff for health. In the subcommittee's view, the need for this type of long-range planning is becoming more and more imperative in order to solve the problems pertaining to the growing competition for resources, the emerging scientific and technical potential for the pursuit of specific objectives, the concern focusing upon the long-term economic and social consequences of Federal research expenditures, and the influence exerted upon the course and direction of science and its relevant institutions.

RECOMMENDATION B: THE NIH SHOULD INSTITUTE NECESSARY REFORMS TO TIGHTEN ITS ADMINISTRATIVE PROCEDURES FOR PROGRAM IMPLEMENTATION

As an adjunct of the subcommittee's review of the organizational capabilities of NIH to conduct long-range program planning, a review also was made of certain aspects of the NIH program administration. This section of the report discusses the subcommittee's review of the administration of (*a*) the Research Career Program; (*b*) research grant

cost analysis; and (*c*) research grants to foreign institutions. Based on this review, the subcommittee is making a number of recommendations which it believes, if properly implemented, should result in a savings of Federal funds and improve the administration of the NIH programs by providing firm criteria uniformly applied.

An attempt was not made to review all aspects of NIH program administration. The Research Career Program was reviewed because this program appeared to have definitive criteria for awards thereunder and to lend itself more readily to administrative review, therefore, than would, for example, a research program wherein grants are awarded primarily on the basis of abstract professional scientific judgment. The subcommittee's review brought out the fact that there are many aspects of the Research Career Program with respect to which NIH has failed to establish clear policies, such as the eligibility of candidates for awards under the program and whether certain types of activities by the grantees should be permitted. Also, as will be shown, NIH was not aware of many deficiencies in administration of the program. Similarly, a review of allowable costs for research grants was made because these also are not wholly dependent upon professional scientific judgment and therefore serve to a degree as a barometer with respect to the control and economy exercised by NIH over the programs. Several weaknesses also were noted here. A limited number of research grants to foreign institutions were examined because of certain balance-of-payments implications and also again because allegedly there are definitive criteria for such awards. The subcommittee's investigation revealed, however, that the criteria are neither uniformly nor accurately applied in awarding such grants.

1. Research Career Program

The NIH Research Career Program was established in fiscal year 1961 under authority of section 301(c) of the Public Health Service Act.[223] The first grant awards under the program were made in fiscal year 1962.

The stated purpose of the program is to increase the number of stable full-time career opportunities for scientists of superior potential and capability in the sciences related to health.[224] Grants are made to public and private nonprofit institutions in the United States on behalf of qualified candidates. Two categories of awards—career awards and career development awards—were initially made under the program. Both types of awards are for 5-year periods; however, the career development award may only be renewed for one 5-year period, whereas there is no limit on the number of renewals for career awards.

Career awards were made from the inception of the program until June 30, 1964, at which time NIH discontinued granting further such awards. The stated purpose of career awards was to enable institutions to finance positions favorable to the intellectual growth and research productivity of established investigators of high competence for the duration of their careers.[225]

Career development awards are intended to enable institutions to finance positions for somewhat younger investigators, that is, qualified scientists who have had 3 years or more of relevant postdoctoral research or professional experience. Such awards are available for

[223] 42 U.S.C. 241(c). See also Public Health Service Regulations (42 CFR, pts. 1 and 61), and Department of HEW Regulations (45 CFR, pts. 6 and 8).
[224] "Policies Governing the Research Career Program of the National Institutes of Health," Jan. 1, 1963.
[225] Ibid.

two groups of scientists: (1) Individuals with clear research potential who require additional training and experience in a productive scientific environment in preparation for careers in independent research, and (2) individuals with demonstrated capacity for independent research who have not yet reached the stage in their scientific development to qualify as established investigators of high competence.[226]

Through fiscal year 1965, PHS had made 3,813 awards totaling $66,380,742 under the Research Career Program. The number of awardees by categories, number of sponsoring institutions, and amount of awards under the program for fiscal years 1964 and 1965 are shown below.

	Fiscal year	
	1964	1965
Number of awardees	1,126	1,199
Career	249	233
Career development	877	966
Number of institutions	164	168
Amount of awards	$19,791,874	$22,426,901

Grants under the Research Career Program are awarded and administered by the nine categorical institutes of the NIH. The terms of award under the program provide that each awardee be directly responsible to the institution to which the award is made and that his status, title, salary, and staff privileges be determined by the institution according to its established policies within the limitations established by the policies governing the Research Career Program.

The terms of award further provide that, although an awardee may participate in teaching or other appropriate functions of his institution, his primary responsibilities must be for the conduct and direction of research and research training; awards will not be made on behalf of persons who will have substantial administrative responsbilities, nor will awards be continued or renewed if substantial administrative responsibilities are later assumed.

The candidate must state his plans for research and other professional activities in the grant application, and the institution must state its plans for the candidate's career, including training opportunities, when relevant.

Since awards are intended to provide institutions with funds to compensate awardees adequately for full-time research and related activities, the terms of award state that awardees should not engage in clinical practice, professional consultations, or similar work, except insofar as these activities are required by their research and teaching or are necessary to maintain their professional skills. Awardees may, however, engage in certain activities, such as scholarly writing, service on advisory groups, and delivery of outside lectures, provided that these activities remain incidental and are undertaken within institutional policy. To be acceptable, a candidate must agree to limit his activities in accordance with these policies.

[226] Ibid.

The sponsoring institution is required by NIH to indicate in the grant application the salary it proposes to pay the candidate. The salary should be based on the candidate's training, experience, and accomplishments, but it may not exceed $25,000 per calendar year. The proposed salary should be based on a full-time, 12-month staff appointment and must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned.

NIH requires that institutions use the award to provide full salary for the awardee. Accordingly, the awardee may not receive additional income for professional services from the institution or other sources. He may, however, retain honoraria, royalties, and fees for such activities as scholarly writing, service on advisory groups, and delivery of outside lectures.

In addition to the base salary, awards under the program may include funds for fringe benefits and indirect costs of the institution.

Under the terms of award, if it is proposed that the applicant institution or other party retain fees accruing from professional practice by a candidate, the full circumstances and facts relating to the fees and the policy of the institution relating thereto must be presented in the application.

The grantee institution is required to submit an annual statement summarizing the awardee's research and teaching activities and the extent and nature of his other activities, such as administrative activities, service on advisory groups, outside lectures, and professional practice and consultations. In addition, an expenditure report is required from the grantee institution within 3 months after termination of the grant year.

Dr. Kenneth M. Endicott, Director, National Cancer Institute, informed the subcommittee that in his opinion research was a young man's game. He stated that often a good investigator will commence to "run down" in his forties and become unproductive in his fifties. He further stated that this was one of the reasons why lifetime awards under the Research Career Program were considered not desirable and were terminated. The Physical Sciences Panel of the Wooldridge Committee expressed the opinion that career development award grantees should be no older than 35 at the time the grant is made and that awards should be limited to 10 to 15 years. However, there are no age restrictions pertaining to eligibility for awards under the Research Career Program.

The subcommittee made a check of career awards under this program and noted that 23 of 24 recipients were over 40 years of age at the time they received the award—3 of these awardees were over 50 years of age and 1 awardee was over 60 years of age. A check of career development awards under this program also was made, and it was noted that 32 of 47 recipients will be over 40 years of age at the completion of their first 5-year award. Moreover, as there are no age restrictions for grantees, it must be assumed that the age factor will not preclude the granting of follow-on awards for an additional 5 years to most, if not all, of these same grantees. Therefore, it appears these scientists were given awards to develop them into proficient researchers at a time of life when it is believed that their age is a deterrent to such proficiency.

At the request of the subcommittee, the General Accounting Office conducted a sample review of awards, amounting to about $4.3 million as of June 30, 1965, made to six grantee institutions on behalf of individual awardees under the Research Career Program. (See app. G, pt. 6 for excerpts from the report to the subcommittee on this review by the General Accounting Office.)

The review was directed toward ascertaining whether the awards were made and the functions of the individual awardees and the grantee institutions were carried out in conformity with the requirements and purposes of the program as set forth in "Policies Governing the Research Career Program of the National Institutes of Health" dated January 1, 1963. Particular emphasis was placed on whether individual awardees were complying with the requirement that they engage in full-time research and related activities, whether individual awardees were receiving compensation for activities not permitted by the terms of the award, and what disposition had been made of income from professional consultations and practice and other outside activities engaged in by the individual awardees.

The review encompassed awards to 6 institutions in support of 73 individual awardees. A total of 43 instances of deficiencies or questionable practices were noted. One or more of these instances were found with respect to 37 individual awardees, including awardees at each of the institutions covered by the review.

Information obtained from awardees and institutional officials indicated that the majority of the 73 individual awardees were then spending at least 80 percent of their time on research or research-related activities. Detailed records giving a breakdown of time were not maintained by the awardees or the institutions; consequently the accuracy of the information could not be independently verified. The review showed that three of the awardees at one institution were enrolled as full-time students and that an awardee at another institution was away from the sponsoring institution from 50 to 75 percent of the time during a 1-year period in connection with his duties as president of a national health association. Although the policy governing awardees' activities does not fully cover the above situations, activities such as these do not appear to be in accord with the intent of the program.

Thirty-five awardees received income from outside sources during calendar years 1963 or 1964 or during both years. The income received by six of these awardees appeared to be contrary to the terms of the grant awards. For 20 other awardees, the information with respect to the nature of the service from which the income was derived was insufficient to enable a determination of whether such income was consistent with the terms of award. Income received by the other nine awardees appeared to be proper under the terms of award of the program.

It was found also that 14 of the awardees remitted income received for professional services to the grantee institution. The income remitted to the institutions was put into special funds and generally was used to support the institutions' research or educational activities. However, at one institution the records showed that certain payments from the special funds were made for the benefit, either directly or indirectly, of individual awardees. Since the terms of award state that awardees may not receive additional income from professional

services from the institution or other sources, such payments appear improper.

At one university it was found that, although the terms of award state that institutions must use the awards to provide full salary for the awardees, 6 of the 15 individual awardees at the university were paid salaries in excess of those approved in the fiscal year 1964 grant awards. The additional salaries, which resulted from university-wide salary or individual merit increases, were paid without prior approval by the NIH from PHS grant funds which were not intended for use in this manner.

It was noted also that three career development awards were made to individuals whose qualifications indicated that they were established investigators whose careers had advanced to a point where such awards did not appear to have been made in accordance with the intent of the program.

Although the review encompassed awards made to only 6 of the 168 institutions which now sponsor individual awardees under the Research Career Program, the General Accounting Office believes that, because of the lack of definitive policies governing the program, the situations noted may exist at other institutions.

The General Accounting Office believes that most of the deficiencies and questionable practices noted during its review may be attributed to a lack of clarity in the NIH policie sgoverning the Research Career Program and to the fact that the NIH do not require awardees and grantee institutions to provide adequate information regarding awardees' outside income, the nature of awardees' activities, and the use of fees remitted to the institutions by the awardees.

The General Accounting Office stated that formal comments of the Department or the institutions visited during their review were not requested on the information contained in their report and accordingly, to that extent, the conclusions and opinions expressed in the report should be recognized as tentative.

Based on the findings developed by the General Accounting Office the subcommittee recommends that NIH revise the policies governing the Research Career Program to clarify the responsibilities of the institutions and awardees relating to outside activities and income and reporting thereon, allowable salaries, and disposition of fees remitted by awardees. In addition, it is recommended that NIH establish firm criteria relating to the eligibility of candidates for awards under the program.

2. Research grant cost analysis

The study sections, in addition to evaluating the scientific merit of proposed research projects, also have responsibility for passing judgment on the equipment and supplies costs, salaries, and level of NIH support for the projects they consider.

A review by the subcommittee of a number of research grant applications indicated that such applications contain very limited amounts of information relative to budgeted expenditures. In making decisions pertaining to the reasonableness of these expenditures, study sections apparently rely on general observations and personal experience rather than on proper cost analyses. The members of the study sections appeared to be knowledgeable in certain instances as to whether equipment and travel were necessary for the

successful completion of the project and as to the reasonableness of the salary of the investigator. However, since they do not always visit the project site and usually do not have personal knowledge of the particular situation (e.g., existing availability of office equipment (unspecified) requested in the grant application), there can be no assurance that excessive budget requests are normally eliminated. Also, although the grant recipient submits expenditure reports annually and at the completion of the grant, such reports are in summary form, and their audits have been very limited. Thus as a practical matter, there is no assurance that the budgetary costs of research grants are reasonable.

The summary sheet for many grant applications reviewed by the subcommittee indicated that "the budget appears to be modest considering the amount of work to be done." However, this statement was based on an overall observation rather than an analysis of individual items. For example, a frequent item was an even $1,000 "for clerical help on an hourly basis." This may be considered a modest sum, and the scientist in the study section responsible for reviewing the application may have been correct in his judgment that clerical assistance would be necessary to successfully complete the project, but the subcommittee cannot help but wonder whether it would not have been beneficial, in the interest of economy, for the reviewers to know how many hours of clerical work were anticipated and the hourly wage to be paid.

There does not appear to be any effective means of determining the necessity for equipment requested in budget applications. For example, a grant for writing a history of medicine of South Carolina to an investigator at the Medical College of South Carolina had an approved budget for the first year of the grant which included (in addition to secretarial wages of $3,000 a year) a typewriter, $225; filing cabinet, $60; and a secretary's desk and chair, $250. The budget for the following year included a "tape recorder for dictation required when the secretary was not available—$180 and microfilms—$100." For the third year of the grant the budget included a microfilm reader—$200. It would appear that as long as the investigator kept his requests relatively modest, no questions were asked, even though (*a*) it would seem that a number of the items requested should have been readily available at the institution and (*b*) it appears odd that all the "required" equipment was not needed from the outset since there was no apparent difference between the work to be performed in any particular year.

It is also pertinent to note, in regard to this same grant, that the secretary originally was to receive an annual salary of $3,000 apparently for full-time effort. In the next budget presentation it was indicated that the salary was reduced to $2,460 annually for only 28 hours of work per week representing 100 percent of her time on this project. The third budget presentation indicated that the annual salary was restored to $3,000 but the effort was to be only 60 percent of the secretary's time (i.e., 17 hours on the basis of the 28-hour week for the previous year) although no indication was given as to how many hours this actually represented. For the fourth year the secretary's annual salary was to be $3,150 for a 30-hour workweek. It would appear that prudent administration would have dictated that these items be questioned.

Another typical example was noted in regard to a foreign grant where a summary statement indicated "in the first year, $3,500 is listed for the purchase of a refrigerated preparative centrifuge, and in the 2 subsequent years, $1,500 and $1,000 respectively for unspecified equipment." It is not understandable how a judgment was made as to the reasonableness of the cost or of the necessity to purchase equipment when the equipment was not specified. This same summary statement also indicated in regard to the budget: "Supplies would come to $2,000 a year, and travel, to $150 in the first year, $300 in the second and third years respectively." Again, it is not understood how a judgment was made when an itemization was not furnished.

Many of the approved grants reviewed by the subcommittee requested certain amounts for domestic travel without indicating where the travel was to take place or why it was necessary or desirable. This does not appear to be reasonable considering the justifications normally required in government and industry. For example, only a limited amount of travel is permitted to an investigator employed in the NIH intramural program and the travel that is authorized is tightly regulated and closely administered. Since this investigator is engaged in projects comparable to the extramural program, it would appear that the investigator in the extramural program could be limited to the same travel restrictions and regulations as the investigator in the intramural program without hindering his efforts.

A report of the House Committee on Government Operations in August 1961, following a review of the administration of grants and awards by the NIH, stated that one of the additional measures needed to improve the effectiveness of the project review system was that the scientific review conducted by the study sections should be complemented by a thorough review of each project's financial requirements performed by qualified analysts in the Division of Research Grants.[227] Although the report pointed out that the study sections do concern themselves with the reasonableness of budget requests in relation to the work proposed, and that this is an essential part of judging a project's feasibility, this, however, is not the type of systematic budget examination that is required to satisfy NIH's administrative responsibility. Moreover, the responsibility for obtaining the efficient and economical use of public funds cannot properly be delegated to advisory bodies.

The Committee on Government Operations made a follow-up review and reported in June 1962 that, although NIH reacted favorably to its recommendation and had indicated that until a plan could be implemented to improve its surveillance of the handling of grants by decentralizing this function to the several Institutes, there had been no significant improvement in the inadequate fiscal review of project financial requirement.[228] The committee further stated that it believed the weaknesses in the grant programs were due in large measure to the failure of NIH officials to understand the nature of their responsibility for the management of public funds. This conclusion was supported by testimony given by the Director of NIH in hearings by the House Intergovernmental Relations Subcommittee in March 1962, in which he stated:

> The recipients are selected on the basis of a rigorous screening by their scientific peers. The idea and the man are both examined with care.

[227] H. Rept. No. 32, 87th Cong., 1st sess., p. 33.
[228] H. Rept. No. 1958, 87th Cong., 2d sess., p. 14.

This is the point at which the really significant administrative actions designed to make the program efficient and productive are taken. Selection of good men and good ideas—and rejection of the inferior—is the key. All subsequent administrative actions having to do with the adjustment of budgets, and so forth, are essentially trivial in relation to this basic selection process.[229]

Although there have been some subsequent changes in the regulations, such as a requirement for prior NIH approval of changes in plans for equipment costing more than $1,000, this procedure appears perfunctory, and in the view of the subcommittee, there does not appear to have been any substantial improvement in the management by NIH of its grant programs.

The Administration Panel, the Microbiology Panel, and the Physiology Panel of the Wooldridge Committee expressed concern over fiscal restrictions on equipment purchases. For example, the Administration Panel reported:

* * * If the purchase [of equipment] costs more than $1,000 any such change now requires prior approval by NIH. Assuming that the local institution has good purchasing procedures and an adequate system of inventory control, the Panel sees no reason why substitutions, regardless of size so long as the year's total allocation for equipment is not exceeded, should need approval except from the local institution. NIH should perhaps be promptly informed, but it is not clear to us what utility this information would have in Bethesda.[230]

It appears, however, that the Panels were unduly concerned with the alleged restrictions on major equipment purchases not identified in the budget requests. No examples were given to indicate that a particular project had been adversely affected. In fact, the Physiology Panel admitted that it saw no evidence of the regulations imposing a hardship on investigators. The limited controls imposed by NIH do not appear to be too stringent. The subcommittee's review showed the administration of controls needs further strengthening and clarification and there does not appear to be any justification for exempting investigators supported by NIH from reasonable fiscal controls imposed on other users of Federal funds.

The subcommittee recommends that NIH install procedures (1) whereby the financial requirements of research project grants would be indicated on the applications in sufficient detail to permit a determination as to necessity and reasonableness, (2) the necessity for personnel, equipment, supplies, and so forth, be specifically reviewed and approved by the study sections, and (3) the reasonableness of the costs budgeted and actual expenditures be subject to review and approval by qualified cost analysts.

3. Research grants to foreign institutions

In addition to the elements taken into consideration in the review of domestic applications for research grants, as discussed earlier, the Public Health Service has established the following further criteria to be applied in determining whether a foreign research grant shall be awarded:

1. The foreign research proposal is of such a nature that the results are likely to advance significantly the status of the health sciences in both the United States and the country of the applicant; and either

2. (*a*) is outstanding or original in concept of (*b*) would utilize talents, skills, materials, or clinical, epidemiological, population, or other resources not likely to be readily available to the United States; or

[229] Hearings before the House Intergovernmental Relations Subcommittee, March 1962, p. 14.
[230] Biomedical Science and Its Administration—A Study of the National Institutes of Health, February 1965, p. 119.

3. is directly relevant to the program objectives and included in definitive program plans of the institute or division concerned.[231]

In view of the U.S. balance-of-payments position, certain restrictions also have been placed on the purchase of equipment with such grant funds. Thus it is apparent that foreign research grant applications are intended to meet more stringent standards in order to be eligible for funding by NIH. Nevertheless, the subcommittee's review of a number of foreign research grants revealed that several such grants were awarded without any apparent indication that the criteria cited above were satisfied.

A statement indicating on what basis, in the opinion of the study section making the initial evaluation, the criteria for awarding a foreign grant application were satisfied is usually set forth in the summary statement prepared by the study section for consideration by the Advisory Council. The summary statement, which contains a brief résumé of the proposed project and of the study section's critique and recommendation, is usually the only document considered by the Advisory Council, since the applications themselves are not made available to the Council. The following are excerpts from summary statements for foreign grants funded in fiscal year 1966 which purport to satisfy the criteria for grants to foreign institutions, but which in the subcommittee's opinion do not clearly indicate that a foreign grant is warranted.

1. (A 3-year grant totaling $38,100): "Dr. _____ is already an outstanding investigator, and his laboratory will, in all probability, become one of worldwide importance."

2. (A 4-year grant totaling $84,000—a continuation of a previous grant for 6 years): "The eminence of the applicant serves to satisfy this requirement."

3. (A 3-year grant totaling $45,000—a continuation of a previous grant for 3 years): "Since closely related research is being done in many American laboratories, the only criterion which warrants a foreign grant is the outstanding record of the applicant. On this matter, the study section was split, 9 to 5, in favor of satisfaction of foreign criteria."

4. (A 3-year grant totaling $343,800—a continuation of a previous grant for 3 years): "With a split vote of 11 to 4, the study section considered the outstanding reputation of the applicant as qualification for a foreign grant."

5. (A 3-year grant totaling $18,600 entitled hereditary infections of sex-ratio in drosophila—a continuation of a previous grant for 3 years): No indication was given as to why it was believed that this grant would satisfy the foreign criteria.

6. (A 3-year grant totaling $36,600 entitled "Role of disulfide bridges in protein conformations"): No indication was given as to why it was believed that this grant would satisfy the foreign criteria.

It will be noted that the mere fact that a foreign investigator may be considered "eminent" or have an "outstanding record" is not a sufficient basis for justifying a foreign grant award, and yet in the six examples cited, these were the only factors mentioned—or none at all—as satisfying the above criteria for such awards.

In the course of the study section and Advisory Council sessions observed by the subcommittee staff it was noted that the members thereof did not appear to have a clear understanding of the criteria for foreign grants. In a number of instances differing opinions were expressed as to what were the criteria, but the text thereof did not appear to be readily available, and the difference was left unresolved. Moreover, in the subcommittee's opinion, the criteria for foreign grants are not significantly different from those applied in the review of do-

[231] Public Health Service Manual, Administration of Grants, pts. V-590A.

mestic grant applications and, furthermore appear vague in that more than one interpretation can be given to various sections.

Consequently, the subcommittee strongly recommends (1) that the criteria to be applied in determining whether a foreign research grant shall be awarded should be made more definitive in order to permit meaningful application and uniform interpretation; (2) that the members of study sections and Advisory Councils be better advised as to these criteria; (3) that the basis of satisfaction of these criteria be clearly indicated on the summary statements for research grant applications recommended for approval which are presented to the Advisory Councils; and (4) that measures be instituted to assure that the study sections and Advisory Councils adhere to the established criteria.

In summary, the subcommittee believes there is an urgent need for NIH to strengthen its capacity for long-range planning and to improve program administration and tighten fiscal controls in order to correct the deficiencies described above.

PART D—THE FOOD AND DRUG ADMINISTRATION

70-135—66——10

Part D—Food and Drug Administration

I. INTRODUCTION

During the course of this subcommittee's investigation, the Food and Drug Administration, like the Public Health Service, (*a*) acquired practically an entirely new management team at the top level, (*b*) was the subject of a special study by an advisory committee appointed by the Secretary of HEW and (*c*) is currently undergoing a series of organizational changes designed to better enable it to cope with its burgeoning responsibilities. The subcommittee has been impressed with the progressive and dynamic image acquired by the FDA as a result of these three factors and with the apparent determination of the new Commissioner to meet head on the many new challenges facing this Agency. Nevertheless there are certain areas in which the subcommittee noted a number of serious, continuing deficiencies, which are set forth below under the subcommittee's findings and recommendations.

In order to gain a fuller understanding of the subcommittee's recommendations, a brief summary of the history and the major new responsibilities of the FDA may be helpful. A further excellent and comprehensive description of the wide range of FDA activities is set forth in the subcommittee print entitled "Background Material," volume II, (pp. 493–589), prepared by the FDA for this subcommittee.

The Food and Drug Act was passed in 1906, after many long and bitter struggles both within and without the Congress. Enforcement of the act was assigned to the Bureau of Chemistry in the Department of Agriculture. In 1912 the regulatory and research functions under the act were separated into two distinct services within the Bureau. However, the two services continued to operate side by side in the Bureau of Chemistry until 1927, when the Food, Drug, and Insecticide Administration was established as a separate unit to conduct the regulatory work, including the scientific research essential to effective enforcement. The name was simplified in 1930 to Food and Drug Administration. In 1940, under the President's Reorganization Plan No. IV, the FDA was transferred from the Department of Agriculture to the Federal Security Agency, which in 1953 became the Department of Health, Education, and Welfare.

The FDA is the Nation's primary protector of the public health with respect to food, drugs, cosmetics, therapeutic devices, and hazardous household substances. Specifically, the Commissioner of Food and Drugs is responsible, under the general direction of the Secretary of HEW, for administering the (*a*) Federal Food, Drug, and Cosmetic Act, (*b*) Federal Caustic Poison Act, (*c*) Import Milk Act, (*d*) Filled Milk Act, (*e*) Tea Importation Act, and (*f*) Federal Hazardous Substances Labeling Act.

The Drug Amendments of 1962 to the Federal Food, Drug, and Cosmetic Act imposed greatly increased responsibilities on the FDA by requiring it to assure a higher degree of safety, effectiveness, and

reliability in prescription drugs and to strengthen its new drug clearance procedures. The FDA has recently modified its organizational pattern for handling the review and surveillance of new drugs, as further described below.

In 1965 the Congress passed the drug abuse control Amendments which provide for increased controls over depressant, stimulant, and counterfeit drugs. This legislation also materially increased the responsibilities of the FDA.

In the food field, while there has been no recent legislation, increasing problems and responsibilities have been created by technological advances in this industry. An increasing variety of chemical food additives are being incorporated in foods to make them more attractive, better tasting and more economical. There are today an estimated 2,200 chemicals used that fall under the FDA's jurisdiction.

Another problem of concern to both consumers and the Government involves the increasing use of pesticides. There are an estimated 500 chemicals used today in approximately 55,000 formulas registered with the U.S. Department of Agriculture.

In recent years there have arisen increasingly complex problems of bacterial contamination of foods. These contaminants range from the deadly botulinus to the discomforting and sometimes fatal Salmonella organisms.

The explosive growth of the FDA in recent years and the growing number and complexity of the problems with which it must deal has made it particularly imperative for the FDA to strengthen its organizational and scientific capabilities so as to be adequately equipped to meet the challenge of these new responsibilities. Thus, as new drugs are developed the FDA must be able to make timely decisions as to a drug's safety and effectiveness, so as to discharge its responsibility to protect the consumer without delaying scientific progress and the availability to the people of this country of new drugs that can save lives or minimize the disabling consequences of disease.

In November 1965 the Secretary of HEW appointed a special advisory committee, under the chairmanship of Rufus Miles, former Assistant Secretary of HEW for Administration, to advise him as to the "current and emerging problems of the Food and Drug Administration." [232] The report of this committee, released in January 1966, drew three basic conclusions about the needs of FDA: [233] (1) There is urgent need for a clear set of written policies to establish clear agency guidelines for decisions involving such difficult issues as—

(*a*) What should be the relative emphasis of enforcement as compared to education and voluntary compliance, and how can these two approaches be combined most effectively?

(*b*) Where should the balance be struck between benefits and hazards in the approval of new drugs?

(*c*) What principles should be used in deciding difficult cases where the issue is between quick action to protect the public against suspected but unproven health risks and more deliberate action to continue known health benefits? (This problem is made especially difficult when large economic losses hang on a close question.);

[232] Hearings, p. 385.
[233] Id., pp. 386-388.

(2) There is a need for a strengthening and reorientation of management, that is, decentralization of decisionmaking accompanied by clear written criteria and guidelines for the decisionmakers in order to assure efficient, effective, and consistent administration; and (3) there is a need to elevate the scientific competence of the FDA.

With respect to the first need, the subcommittee was advised subsequent to the hearings that the FDA has prepared and recently distributed a "Bureau of Medicine Manual of Policies and Procedures," in looseleaf form to permit periodic updating. With respect to the second need, the subcommittee was advised in the course of the hearings that the FDA district office directors would be given increased responsibility and more direct access to the Commissioner of Food and Drugs.[234] With respect to the third need, the subcommittee noted with approval the recent consolidation by the FDA of the former Bureau of Scientific Research and Bureau of Scientific Standards and Evaluation into a single, strengthened Bureau of Science.[235]

II. FINDINGS AND RECOMMENDATIONS

Despite the organizational and administrative improvements recently effectuated by the FDA, the subcommittee's investigation revealed that a number of deficiencies continue to exist which seriously limit the effectiveness of the FDA's programs. The findings and recommendations of the subcommittee in this regard follow.

RECOMMENDATION A. THERE IS A NEED FOR CLOSER COORDINATION OF THE FDA'S PROGRAMS WITH THOSE OF OTHER DEPARTMENTS AND AGENCIES IN AREAS OF OVERLAPPING JURISDICTION

In view of the broad range of its responsibilities, the FDA's programs necessarily overlap those of a number of other departments, as well as other agencies both within and without the Department of HEW. The need for effective coordination of such overlapping programs is therefore particularly paramount in the case of the FDA.

One of the most important areas in which the FDA has overlapping jurisdiction is with respect to the use of pesticides, where the FDA shares joint responsibilities with the Departments of Agriculture and Interior and several divisions of the Public Health Service, including the Division of Environmental Engineering and Food Protection. The subcommittee was advised by Department representatives that close cooperation was being achieved in this area.[236] This was not borne out, however, in statements made to the subcommittee staff by field representatives in the HEW regional offices and the FDA district offices, who indicated that there is very little active cooperation or coordination between these units. Thus there apparently still exists a need for closer cooperation between the FDA and the PHS in their field operations. In this connection, it is worthy of note that the report of the recent FDA advisory committee, headed by Rufus Miles, also cited the need for greater cooperation between FDA and the NIH and the need for a more fruitful relationship between the FDA and the Department of Agriculture and the Veterans' Administration.[237]

[234] Id., pp. 392-395, 433. See also app. H, pt. 1.
[235] Id., pp. 390-393. See also app. H, pt. 1.
[236] Id., pp. 385, 403-404.
[237] Id., p. 387.

RECOMMENDATION B. THERE IS AN URGENT NEED FOR IMPROVED CONTROLS BY THE FDA TO ASSURE THE SAFETY AND EFFECTIVENESS OF FOREIGN DRUGS

The Second Citizens Advisory Report of 1962 indicated that the FDA control measures over drugs manufactured in foreign countries were seriously deficient. The subcommittee's investigation revealed that there has been no substantial improvement in this regard.

The 1962 Kefauver-Harris drug amendments gave the FDA authority for stronger control over both domestic and foreign drugs. The import provisions of the law were intended to assure the same degree of reliability for imported drugs as for domestic drugs. The law provides that unless a foreign shipper is registered with the FDA, every shipment of drugs from that firm offered for entry into this country must be sampled and examined. It also provides that foreign firms shall be permitted to register pursuant to regulations to be promulgated by the FDA. The subcommittee was astonished to learn, however, that no regulations have even been issued yet by the FDA pursuant to this authority.

The subcommittee's hearings brought out the fact that not only is the FDA's inspectional coverage of foreign drug manufacturers that ship to the United States so infrequent as to be of little or no value,[238] but also the fact that a great many of such drug shipments are not sample tested by the FDA, as required by the 1962 law.[239] Information provided by the FDA itself revealed that there were approximately 1,000 commercial shipments alone into this country last year that were not tested by the FDA, plus an unknown number of private drug shipments.[240] The seriousness of this situation is apparent from the FDA's own statements before a sister committee last year, that—

> The 8,500 commercial and the uncounted number of private imported drugs present every problem encountered in domestically produced drugs, but consumer protection is made even more difficult because FDA lacks basic intelligence data about foreign manufacturing practices and controls. The problem is further complicated by variations in foreign standards of control, labeling, packaging, and other critical phases of pharmaceutical production.[241]

FDA representatives stated to the subcommittee that the FDA has been unable to obtain a sufficient number of inspectors to test every foreign drug shipment as required by law, but that additional inspectors would be added this year to monitor international shipments of both food and drugs.[242]

The subcommittee also was informed by the Commissioner of Food and Drugs that the FDA would create a new Office of International Affairs and that one of its first missions would be to provide the necessary safeguards to make certain that imported drugs meet the same standards as those required of U.S. manufacturers.[243] The subcommittee endorses this move and recommends that one of the first tasks that should be assigned to this new Office is the preparation of regulations establishing requirements and procedures for registration of foreign drug manufacturers as contemplated by the 1962 law.

[238] Of the 43 foreign drug manufacturers who have made sales of certifiable antibiotics to U.S. purchasers 12 have not been inspected at all by the FDA since 1962 and 25 others have been inspected only once since, 1962.
[239] Hearings, pp. 424–426.
[240] Hearings before the House Appropriations Committee, 1967 HEW budget, pt. 2, p. 105.
[241] Id. at 104; see also hearings, pp. 424–426.
[242] Hearings, p. 425.
[243] Id., pp. 394, 425.

RECOMMENDATION C. THERE IS A NEED TO CLEAR THE PERENNIAL BACKLOG OF AND EXPEDITE CLEARANCE PROCEDURES FOR INVESTIGATIONAL AND NEW DRUGS

Despite some recent improvement, FDA officials conceded that the perennial backlog of applications in regard to investigational and new drugs still exists.[244] The subcommittee was informed that a recent reorganization of the Bureau of Medicine, approved by Secretary Gardner on July 11, 1966, should substantially eliminate this backlog by the end of 1966.[245] It is expected that this will be accomplished by a "team" approach whereby a single group of medical officers will handle drugs which are similar in structure or use at both the investigational and approval stages [246] and by the assignment of a number of PHS physicians to assist in breaking this blacklog.[247]

The subcommittee endorses both of these measures and recommends that the FDA continue to place a high priority on clearing these perennial backlogs and that it carefully monitor the effectiveness of the reorganization of the Bureau of Medicine to accomplish this task.

RECOMMENDATION D. THE DEPARTMENT OF HEW SHOULD CONSIDER TRANSFER OF THE DIVISION OF BIOLOGICS STANDARDS TO THE FDA

One of the anachronisms brought out by the subcommittee's investigation is the continued existence of the Division of Biologics Standards under the NIH. The primary responsibility of the DBS is administration of those sections of the PHS Act pertaining to the sale of biological products in interstate commerce. Although a substantial research effort is an integral and necessary part of the DBS activities, it has primarily an endorcement mission, like that of the FDA, rather than a research mission. In fact, biological products in general are less stable than other drugs and are susceptible to at least the same, if not greater, production deficiencies as other drugs. However, the DBS has filed a de minimis number of enforcement actions over the years (in fact, none between 1915 and 1962), and it is apparent that it operates with a much less strict enforcement attitude than does the FDA.[248]

The subcommittee recommends that the Department of HEW give serious consideration, therefore, to transfer of the Division of Biologics Standards from the NIH to the FDA.

[244] Id., pp. 409–411.
[245] Id., pp. 395, 409–411; see also app. H, pt. 2.
[247] Id., pp. 395, 409–411, 433–434.
[246] Id., pp. 396–397, 409–411.
[248] See app. H, pt. 3.

PART E—BIOMEDICAL COMMUNICATIONS

Part E—Biomedical Communications

In an age when a message travels around the world in a second, it is unthinkable that it should take months or even years for physicians and their patients to learn essential medical truths.[249]

I. Introduction

This section of the subcommittee's report reviews briefly emerging Federal policy and past Federal legislation, summarizes the major Federal resources, mentions a few conspicuous deficiencies in the biomedical information exchange, describes the growth which contributed to current difficulties, identifies some of the needs for biomedical information in the current setting, comments briefly on techniques applicable to relieving these needs, looks toward the prospects for automation, reviews the efforts at coordination among departments and within the Department of Health, Education, and Welfare, discusses the biomedical information facilities of the Department of Health, Education, and Welfare, refers to efforts at international communications, offers recommendations for reorganization of biomedical communictions in PHS, and concludes by summarizing the responsibilities and duties of the Department in biomedical information.

The modern scientific era is regarded as beginning in the mid-17th century. Since that time, the fund of human knowledge is estimated to have doubled about once every 15 years. To judge by the volume of scientific literatures today we know about 2 million times as much about the universe we live in and the creatures which inhabit it as was known shortly after the death of Galileo. And according to this formula we'll know 4 million times as much by 1980.

This knowledge explosion of recent decades has literally stunned the world of science. Future scientific progress will command a revolution in the nature and scope of information requirements. Fortunately, advances in communications technology make it possible to satisfy these requirements. To do so, however, we need to develop new, or modify existing, institutions to handle health information in forms and at levels dictated by the needs of these times.

Today, responsibility for scientific communication is no longer that of scientists alone. The task is in the public domain. Now that scientific research is an important instrument of national policy, the Government has the obligation to satisfy the public that the massive social investment in research is soundly managed.

The Federal Government has been given a clear mandate by Congress and substantial resources to support the generation of health knowledge through biomedical research.

The communication of health information is not the responsibility of the Federal Government alone, however. All those in the health industry, a $40 billion enterprise—the research scientist, the physician,

[249] Report of the President's Commission on Heart Disease, Cancer, and Stroke, op. cit., vol. II, p. 43 (1965).

the nurse, the public health worker, editors of scientific journals, science writers, and information specialists, both within and outside the Government—share this obligation. So do those who have the duty to inform the public. The task of realizing and applying the results of research is a responsibility shared by lay and professional workers.

Nevertheless, in the field of the health sciences and their application to health programs, the Department of Health, Education, and Welfare has a central responsibility. The National Library of Medicine of the Public Health Service has a congressional mandate to apply its information resources broadly to the advance of medical and related sciences.

The Public Health Service is required by law to make research and other health findings widely known to the medical profession and to the public.[250] Section 301 of the Public Health Service Act makes it the responsibility of the Public Health Service, under the direction of the Surgeon General, to conduct and support research, training, and other activities relating to the medical and related sciences to protect and improve the health of the people of the Nation. To carry out this responsibility, the Surgeon General is authorized, among other things, to collect and disseminate through publications and other appropriate means, information as to, and the practical application of, such research and other activities; and to make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research or research training projects as are recommended by the appropriate national advisory council established under the Public Health Service Act. Upon recommendation of the appropriate national advisory council the Surgeon General may adopt such additional means as he deems necessary or appropriate to carry out the purpose of this section.

The appropriations made to the various National Institutes of Health for, among other things, grants for research projects and research training grants pursuant to section 301 of the Public Health Service Act, also include funds for the dissemination of scientific and technical knowledge pertaining to such research activities.

The Comptroller General of the United States has ruled that grants-in-aid under section 301 are not limited to grants for research projects such as are specifically authorized by subsection 301(d), but that, in view of the authority vested in the Surgeon General under subsection 301(h), to adopt such "additional means as he deems necessary or appropriate" grants may be made as well for other purposes determined by the Surgeon General to be necessary to carry out the purposes of section 301.

II. Major Deficiencies

One of the major deficiencies of the biomedical structure is the absence of a system of single focal points in each agency, one in the Department of HEW, as well as one for the Federal Government as a whole for collecting and relaying biomedical information effectively. Early efforts by the National Science Foundation, and subsequent efforts by the Office of Science and Technology and the Committee of Scientific and Technical Information (COSATI) of the Federal Council for Science and Technology have not succeeded in establishing such focal units. The Science Information Exchange, the National

[250] Sec. 301 of the Public Health Service Act, 58 Stat. 691, as amended, 42 U.S.C. 241 (supp. IV).

Referral Center, the National Library of Medicine, the Research Grants Index, and a variety of special sources, as well as the internal reports of several departments, offer useful assortments of biomedical information, but no one unit has the duty or capacity of identifying, characterizing, or reporting the information resources for the biomedical field as a whole.

In the absence of a system of focal points for access to sources of biomedical information, many searches and other health activities are unnecessarily duplicated. Others are in conflict with one another. Some are irrelevant. And still others are neglected and overlooked.

The Federal system has no facility with responsibility for collecting and organizing biomedical information which does not appear in the formal literature. This neglected category of "unpublished" literature includes information presented more or less informally at meetings, reports to Government agencies such as the Food and Drug Administration, medical or clinical records, letters, advertisements, films, and unpublished reports of research which include much valuable information about so-called negative results.[251]

Much scientific search produces what are sometimes called "negative results"; i.e., studies which fail to authenticate a particular hypothesis. But what is negative to one scientist may be "positive" to another. For one thing, a scientist may not wish to research an experiment which earlier proved unsuccessful. For another thing, he may find valuable a conclusion which the prior searcher found valueless.

The Journal of the American Medical Association, on the occasion of instituting a Section on Negative Results, stated:

> There exists a rarely defined, but omnipresent reluctance to publish reports of "disappointing" conclusions. Therefore many of these studies are never completed or if completed are not submitted for publication. Since similar paths of research may be traversed repeatedly, the continuation of a trend based upon these attitudes could mean a serious loss in time and effort for clinicians and investigators in the medical sciences. Should it not be assumed that a significant percentage of all clinical observations and research projects will result in unexpected, hence "negative" findings? The negative result can become the impetus for element in progress. Only a carefully documented negative study can correct misconceptions which are of recent vintage or those honored by decades of fallacious repetition.

F. Ellis Kelsey, Ph. D., Office of the Surgeon General, U.S. Public Health Service, has pointed out that the very concept of "negative results" can be harmful. To illustrate, the kidney toxicity of diethylene glycol was well understood by the manufacturer of the solvent long before it was used by a pharmaceutical company in the compounding of the infamous "Elixir of sulfanilamide," which resulted in over 100 deaths and the 1938 revision of the Pure Food and Drug Act. As far as the original manufacturer was concerned, the kidney toxicity was a "negative result" since it meant the solvent could not be used for drugs; this information was "proprietary" in the sense that it was "unpublished" but it was neither "unevaluated" nor intentionally "secret". It was unpublished because there was no economical route for publication, not because the owner wanted to keep it to himself.

Other examples of potentially valuable but underused unpublished scientific data can be found in hospital records, and in reports first printed in newspapers or magazines (and therefore not acceptable to

[251] Report of the President's Commission on Heart Disease, Cancer, and Stroke, vol. ii, p. 431, 1965.

many journal editors). The bulk of unpublished scientific information, apart from the "negative" finding, consists of literature classified as secret by proprietary or military interests.

III. Major Federal Biomedical Activities

Major Federal collections of scientific documents are in the Library of Congress, the National Agricultural Library, the National Library of Medicine, the Science Information Exchange, and the Clearinghouse for Federal Scientific and Technical Information. Major medical information resources in the United States are described in appendix I, part 1.

The first three collections are composed mainly of reports of research results and associated information. The National Library of Medicine is the most comprehensive single collection of formal biomedical literature anywhere. The SIE collection consists wholly of reports of research in progress. Its main task is to enable administrators to review the allocation of research funds and activities, but it is useful also in some situations for advising scientists what others are undertaking in a given field. The Clearinghouse deals entirely in unclassified technical reports issued by Government agencies. It announces them, distributes notices to specialized users according to their interests, and provides copies on request.

The Department of Health, Education, and Welfare has the primary Federal responsibility for health and health-related programs, although many other Government agencies also are heavily engaged. Coordination and collaboration among constitutent agencies and departments must be fostered continuously. At the same time specific missions of each department and agency require that each be supported by science information activities essential to their success. Therefore, what may seem to be duplications among scientific and technical information services frequently are actually guarantees of effective performance. These resources are comparable to the standby crews of the airlines.

The *National Library of Medicine* is the prime Government unit for the collecting, preserving, and indexing of health science publications, and for the Federal programs which are aimed at insuring an efficient and productive national health science information system.

The *Office of Science and Technology* of the Ecxeutive Office of the President is concerned with all administrative aspects of science and technology, including the handling of scientific and technical information. Federal Government organizational adequacies and program effectivenesses are continually reviewed; recommendations for change are arrived at after study by interagency groups (e.g., the Committee on Scientific and Technical Information) (COSATI) and by committees of non-Government experts (e.g., the President's Science Advisory Committee) or ad hoc panels (e.g., the Panel on Handling of Toxicological Information), with additional resource support provided by special studies done under contract as required. The Interagency Committee (COSATI) has been organized into a series of special panels or task forces, each serving a particular area. The committee itself has one member from the Office of the Surgeon General (PHS) and an observer member from the National Library of Medicine. The panels are staffed by additional DHEW personnel, thus

facilitating a broadly based exchange of understanding about programs and activities in all agencies.

The *National Science Foundation*, through its Office of Science Information Services (OSIS), has prime Federal responsibility for the support of national (as contrasted to Federal) scientific and technical information systems in all fields of science and engineering. Thus, NSF/OSIS must be fully and currently aware of existing and prospective science information systems, programs and activities, both in and out of Government. NSF carries out a formal survey of Government scientific and technical information programs each year for its survey of science resources series (Federal funds for research, development, and other science activities). In addition, NSF prepares each year a collection of abstracts entitled "Current Research and Development in Scientific Documentation" and publishes bimonthly a news booklet entitled "Scientific Information Notes." Projects which are important to both NSF and NLM may be partially funded by each agency. The Director of NLM is a member of the Science Information Council of NSF. The NLM Board of Regents has one ex officio member from NSF.

The NSF also supports the *National Referral Center for Science and Technology Information* (NRCSTI) operated by the Library of Congress. This Center has collected and organized information about the Nation's sources of scientific expertise so as to refer inquiries of a scientific or technical nature to the most appropriate organization or individual for reply. Agencies in DHEW supply requested information to SIE and NRC.

The *Federal Clearinghouse for Scientific and Technical Information*, (FCSTI) operated by the Department of Commerce, is an outgrowth of the recognition, by COSATI and OST, that a single outlet was desirable to announce and distribute the reports of federally sponsored research and development. FCSTI collects, indexes, announces and provides copies of unclassified Federal research and development reports to Government agencies, their contractors, and to other manufacturers, research, development and engineering groups, and others. Certain of these reports are selected by NLM for indexing by the NLM medlars and announcement in Index Medicus. FCSTI also operates a translation registry. NLM selects certain titles from the total collection and announces the availability of these translations specifically to the biomedical community on a semimonthly basis.

The *Federal Library Committee* was established in March 1965, in recognition of the need for cooperation and concerted action among Federal libraries. Chairman of the Committee is the Librarian of Congress, who also is a permanent member, along with the Director of NLM, the Director of the National Agricultural Library (NAL), and representatives from the executive departments, including the librarian for HEW. Six other members, representing six of the independent agencies, selected by the permanent members, serve 2-year terms. Observers include a representative of the Bureau of the Budget, the Deputy Librarian and the Assistant Librarian of Congress, and the technical assistant to the Director, Office of Science and Technology, Executive Office of the President.

Six task forces have been established by the Committee to conduct studies and make reports. These task forces deal with automation; acquisition of library materials and correlation of Federal library

resources; the mission of the Federal library; standards for Federal library service; procurement procedures in Federal libraries; interlibrary loan arrangements for Federal libraries; and the recruitment of personnel for Federal libraries. NLM has a staff member on each task force with the exception of recruitment of personnel.

The *Library of Congress* has long had close working relations with NLM, particularly in acquisition, cataloging, and classifying. Although NLM is the only national library which uses computers for indexing searching and retrieving titles, both LC and NAL have been consulted and kept informed by NLM. Employees of the three units meet regularly to discuss plans and implementation of automation in libraries. Participating in these meetings are systems analysts, librarians, and subject specialists from each library.

Although there is a degree of overlap in the scope of the collection at NAL and NLM, there are also many similarities in the methods used by these two national libraries for the handling of their collections. Each collects, indexes, and announces the items most in demand by its respective clientele. At the same time, both depend on each other for much material which has only secondary value to the borrower. This division is dynamic rather than static; user-needs control the nature of each collection. Interagency collaboration is helped through both formal and informal channels, developed directly and through COSATI. The Director of NAL attends all meetings of NLM's Board of Regents.

Chief interest in drug information in the Department of HEW, is in the *Food and Drug Administration* which has assembled a file of clinical reports of experience with drugs and other commodities under its jurisdiction. More than 80 percent of these items concern drugs. The FDA now has about 15,000 items on file and expects to add 1,000 a month. While it works closely with the National Library of Medicine, the FDA finds it must index its files more intensively and provide a more comprehensive coverage to meet the needs of its clientele.

NLM, FDA, and NIH allhave a strong interest in the chemical structural index which initially was financed jointly by HEW, DOD, and NSF. At present, however, this project seems wholly dependent on NSF, although it is expected to be the key to all drug literature.

In summary, the National Library of Medicine is the principal governmental agency for the collection and storage of scientific and technical documents of importance to health workers. Although many of these scientific materials are handled by institutions or other governmental units as well, redundancy in the collecting and handling of such information resources frequently may be desirable in order to facilitate access to documents in demand.

IV. HEW Role in Biomedical Communications

The biomedical communications crisis has highlighted the need for specialized information sources to supplement the broadly based libraries. Under authority of the Public Health Service Act of 1944 and its amendments, the Public Health Service broadly supports such services through grant and contract programs. Others are supported by the Food and Drug Administration, the Office of Vocational Rehabilitation, and the Office of Education. Departmental support has been given to more than 90 special biomedical information centers

through grant or contract and more than 40 are in the Department structure. See appendix I, parts 2 and 3.

The National Library of Medicine

For comprehensive services and support, libraries, specialized information centers, and other users of biomedical information look to the National Library of Medicine.

Established as the Library of the Army Surgeon General before the Civil War, the National Library of Medicine was transferred to the Public Health Service in 1956 as the result of passage of the National Library of Medicine Act of 1956, amending the Public Health Service Act. Services of the Library of the Army Surgeon General were originally open to the public under the provisions of Joint Resolution No. 8 of the 52d Congress (1892) and language contained in the 1901 Appropriations Act for the Geological Survey.

The NLM serves as the dominant source of biomedical materials in the United States. Its collection of nearly 1,250,000 books, journals, theses, photographs, and other records relating to the health sciences is accessible to researchers, practitioners, educators, and the public. Biomedical libraries throughout the Nation are served through interlibrary loan of materials not in their collections and through centralized cataloging. Specialized information centers as well as biomedical libraries rely on the extensive collections of the NLM to supplement their own files. Similarly NLM's cataloging and bibliographic services enable all users to keep up effectively with the growth of biomedical information.

The initial application of advanced electronic information retrieval techniques to NLM operations occurred with the development and implementation of the computer-based MEDLARS (Medical Literature Analysis and Retrieval System). This system automated bibliographic services of the NLM and pioneered in adopting information retrieval techniques to such services. Computer-prepared bibliographies help users select material pertinent to their area of interest. The impetus to develop this system arose from the inability of conventional methods to keep up with the input for the Index Medicus, an indispensable guide to current serial or journal literature in the biomedical field. With MEDLARS, the system prints the index and recurring bibliographies in medical specialities (such as rheumatology, dentistry, and medical education), as well as special bibliographies on demand by individual researchers. The number of articles listed by subject in NLM's computer files since January 1964 now exceeds 400,000. The MEDLARS potential is adding to the biomedical communications network by providing its basic computer tapes and programs to regional centers which may prepare additional recurring and customized bibliographies for institutions, researchers, educators, and practitioners.

The NLM continues to introduce modern information handling and automated processing systems into its operations. Recently, NLM has undertaken to automate catalog services to medical libraries of all types, at a substantial saving in man-hours. The NLM also employs an automated rapid cataloging system which now produces the NLM's Current Catalog. This new biweekly publication permits the biomedical libraries to acquire materials more easily for their collections, and eliminates duplicative cataloging with significant national savings.

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Research and development at the NLM aims to expand its capacity to provide bibliographic control of traditional forms of information and to develop capacities to handle and transmit information in other forms. Use of such forms as facsimile transmission and graphic image storage and retrieval will be explored.

The most important goal of the NLM is the systematic organization of an active biomedical communications complex. This goal requires conversion of local and regional medical libraries from passive information storage facilities to active communication centers anticipating and satisfying the information needs of the community. A conversion implies building both NLM and network information stores and developing the ability to select and transmit needed information rapidly. Such a system can be built in part by reinforcing and developing the current biomedical library facilities, as a base for expanded services.

The existing library system suffers extreme strains on collections, facilities, and personnel. The dramatic growth in the volume of health science information and in the size of the biomedical community and its activities has seldom been matched by expanded library staff and services. Support for the local and regional library has remained relatively constant in the face of the biomedical information explosion. One observer concluded:

> The difficulties of American medical libraries and the effect of their weaknesses on medical research, teaching, and practice should be recognized as a problem of national proportions, one which ultimately may pose a serious threat to the well-being of the American population.[252]

Until recently NLM resources were limited to conventional library work. In 1964, NLM began to administer a program of financial support for research, fellowship, traineeships, and grants-in-aid for the training of librarians in the health communications area under section 301 of the Public Health Service Act. In 1965 Congress responded to the needs of medical libraries, and the Medical Library Assistance Act (administered by the NLM under delegation of authority from the Surgeon General) was enacted providing for financial support of—

(1) Construction and expansion of medical libraries;
(2) Development and expansion of medical library resources and technology;
(3) Conduct of research and development in health related library science:
(4) Training of medical librarians and other information specialists in the health sciences;
(5) Biomedical scientific publications;
(6) Special scientific projects and scholarly works; and
(7) A national system of regional and branch medical libraries.

The vital point in the transfer to the health practitioner of new information is the local library, the base element in the national network. Scott Adams, Deputy Director of the National Library of Medicine, has pointed out that: "Hospital medical libraries have an unrecognized potential as bases of continuing education programs." [253]

Hospital or other local medical libraries in colleges, education institutions, medical societies, or other medical agencies will be called

[252] President's Commission on Heart Disease, Cancer, and Stroke, vol. II, p. 384, 1965.
[253] Hospitals, "Hospital Libraries: Underdeveloped Base for Continuing Education," June 16, 1964, vol. 38, p. 53.

on to develop broad programs of service to various information needs of the health practitioner. Audiovisuals, electronic displays, microforms, programed instructional materials, and other new information methods will supplement traditional resources and will be adopted for user needs in every community, even for the rural practitioner. The local library will be supported by a regional library that will provide extended services of uncommon use.

Deficiencies in the biomedical library network are not exclusively at the local and regional level. An essential ingredient of a viable communications network is a strong central resource. For a biomedical library network, the National Library of Medicine provides the base for a National Coordinating and Switching Center. It is a library's library providing archival, bibliographic, indexing, cataloging, and dissemination functions for medical libraries even on an international scale.

If these functions are expanded and improved, the libraries may begin to meet increased demands for service. Important new functions also can be performed by the National Medical Library to meet these demands.

New central functions

One new function essential to the growth and progress of biomedical communications is research in biomedical information and its processing. For the past few years, medical librarians and other specialists in health communication have been occupied in trying to accommodate the expanding volume of biomedical materials and demands for service. Basic research in modernizing and improving medical communication has been limited. New methods of accumulating information and providing it quickly and efficiently to the vast biomedical community have not been thoroughly explored or placed into operation. Even the triumphal achievement with MEDLARS has been a mere beginning toward satisfying user needs. As the Senate Subcommittee on Reorganization and International Organizations has declared, "MEDLARS may already be obsolete because of the pace of developments in electronic technology." [254]

Need for research and development

Methods to handle important but unpublished data, to provide full descriptions of published work, to extend the responsiveness both in time and completeness of the biomedical library network need to be explored, tested, and adopted. These methods can be found. This need for effective research and development has been sensed by many authorities. One has stated: "Capability to conduct research on information systems will be required, and staff units possessing this capability should be a part of every major unit in the national network of systems." [255]

While some research and development in biomedical communications has been conducted, current theoretical investigations are dispersed and new systems are not being tested under controlled conditions. As a result, many new ideas for improvement of existing systems have had to be rejected for lack of data. Those ideas that

[254] Subcommittee on Reorganization and International Organizations of the U.S. Senate Committee on Government Operations, "Report on Interagency Drug Coordination," p. 122.

[255] U.S. Federal Council for Science and Technology, Committee on Scientific and Technical Information, "Recommendations for National Document Handling Systems in Science and Technology."

have been incorporated into existing systems were done so with a high risk of failure because there was no operating experience.

Studies of prototype systems, simulating operating conditions and requirements, would permit realistic evaluation of proposed systems and systems changes. Additional research and study would be useful to evaluate electronic data transmission, graphic storage and retrieval, and other potential technical advances. Other research could be directed at information retrieval techniques, design of systems based on user capacities and patterns, computer manipulation of natural language, and specialized computer software for information retrieval.

The system also requires development and distribution of biomedical audiovisual and other learning resources, particularly for the continuing education of health practitioners. The chief center of such work in PHS is the Medical Audiovisual Branch at the Communicable Disease Center. This branch—

(1) Develops, produces, distributes, evaluates, and promotes the utilization of motion pictures, television productions, and other audiovisuals;

(2) Provides consultation in the development of specialized audiovisual visual communications activities;

(3) Encourages the production and dissemination of medical films and other audiovisuals elsewhere;

(4) Administers a national medical motion picture archive;

(5) Exchanges scientific and other medical audiovisuals on a national and international basis.

The proliferation of units collecting, processing, and disseminating biomedical information demands improved methods for channeling information users to information sources. A national biomedical clearinghouse and referral center should be established to perform that function. Emphasis should be placed on identifying data of interest to common users, directing users to information contained in specialized information centers, and collecting forms of data which might otherwise be lost, such as unpublished reports, negative reports of scientific investigations, and translations. A single point of entry into the many complicated information systems in the biomedical communications network would result from the establishment of such a center.

As previously mentioned, the multiplication of the forms for transmitting useful biomedical information, combined with its total growth in volume of information, tend to frustrate the user rather than help him. While there are clearinghouses for scientific information, none cover broadly the biomedical area. The Subcommittee on Reorganization and International Organizations of the Senate Committee on Government Operations in its "Report on Interagency Drug Coordination" cites extensive support for its belief in establishment of Federal medical clearinghouses.[256]

Food and Drug Administration

The information explosion has not bypassed regulatory agencies. As the trend in food and drug control has shifted from regulation after the fact in the form of citations, seizures, and prosecutions, to control by preclearance approval, the FDA has been the recipient of large

[256] Subcommittee on Reorganization and International Organizatons of the U.S. Senate Committee on Government Operations, "Report on Interagency Drug Coordination," pp. 116–119.

amounts of scientific and medical data submitted by petitioners in amounts of requests for approval of new drugs, food and color additives, and pesticide tolerances. More than 80 volumes containing information dealing with a single new drug application is an example of the magnitude of information reaching the Division of New Drugs, to illustrate the complexity of the task of reviewing the evidence in support of a single unit of a complex operation.

The need for an effective system to coordinate the large volume of scientific information generated by the FDA and the regulated industry was recognized several years ago and emphasized by several congressional committees. A report by an internal FDA committee recommended the use of a specialized outside consultant to study the feasibility of a science information system for the agency. Such a study was performed by Arthur D. Little, Inc., of Cambridge, Mass., whose report of July 1964 concluded that an overall, integrated agencywide system is feasible and could be implemented within a 5-year period. In December 1964, a second contract was awarded to Arthur D. Little for the detailed design of the basic components of the system. The reports under this contract were delivered in December 1965.

To provide leadership and coordination in the development, implementation, and operation of the agencywide system, a science information facility was created in 1965 within the Office of the Assistant Commissioner for Science Resources (since changed to Associate Commissioner for Science [257]). This Office, headed by the Science Information Coordinator, is responsible for developing the system.

The highest priority has been assigned to the development of those portions of the system dealing with medical problems to serve the immediate needs of the operating program staff in the Bureau of Medicine. This covers two areas: (1) Basic pharmaceutical information derived from new drug and investigational new drug applications, and (2) an interim adverse reaction reporting system. In this area where program needs are urgent, an operating system is being developed, recognizing that some portions of it may later need revision to fit within the overall science information system as it evolves.

At the present time, an operating pharmaceutical information system is in existence that is capable of providing medical and other professional personnel in the Food and Drug Administration with the following types of information extracted from new drug and investigational new drug applications dealing with human drugs: the FDA assigned number, trade and generic names, all ingredients, and the quantitative formula and chemical structure. Additional information parameters soon to be added include therapeutic uses and clinical investigators.

During 1965 the development and design of an interim internal adverse reaction reporting system was begun by the development of codes, vocabularies, and computer programs. The subcommittee was informed that this system will continue to operate until it is either replaced or phased into the comprehensive processing system for reports of adverse drug reactions and hazardous substances injuries which was designed by Arthur D. Little in October 1965, as part of the overall system.

The adverse reaction reporting program is a surveillance system begun by the FDA in 1960 whereby designated hospitals and physi-

[257] See hearings, pp. 389–390.

cians routinely scan their clinical facilities for drug reactions and report this information to the FDA. At the present time the program includes approximately 120 hospitals reporting under contract and approximately 400 governmental institutions, including those of the Army, Navy, Air Force, Veterans' Administration, and the Public Health Service.

The American Medical Association also maintains an adverse reaction reporting program utilizing private physicians and hospitals. Negotiations are underway looking to an exchange of information with that organization.

Under the Kefauver-Harris amendment to the Food, Drug, and Cosmetic Act, drug manufacturers holding approved new drug applications must now forward at regular intervals to FDA information received regarding adverse reaction to approved drugs.

The FDA's field offices frequently receive direct reports of adverse reactions from individuals, private physicians, and hospitals. These are followed up by an experienced inspector, and a report is submitted for evaluation by the adverse reaction reporting program.

Reports of adverse reactions are received from research centers including the National Institutes of Health, and from clinical investigators of their experience with drugs used in their studies.

Approximately 275 major medical journals from all over the world are scanned for reports of adverse reactions appearing in the literature. Information from the articles in 2,600 journals scanned monthly by the National Library of Medicine for drug toxicity is received by FDA from the MEDLARS program.

State departments of health have been requested to forward reports of adverse reactions that come to their attention. Abstracts of these reports are accumulated and published by FDA in a Journal of Literature Abstracts which is distributed to participants in the adverse reaction reporting program.

On April 21, 1965, the President approved a proposal to offer FDA facilities to the World Health Organization for the collection, storage, and retrieval of adverse drug reactions on an international basis to develop a worldwide early warning system for drugs. Such an International Adverse Drug Reaction Center would be similar to WHO-designated centers in other fields which are currently in operation in the United States and other countries. These centers include: the International Shigella Center at the Communicable Disease Center of the Public Health Service in Atlanta; the International Rickettsial Disease Center at the Rocky Mountain Laboratory of the National Institutes of Health in Hamilton, Mont.; the International Center for Biological Standards at the State Serum Institute in Copenhagen, Denmark; and the World Influenza Center at the National Institute for Medical Research in London, England.

To allow meaningful analysis of the information in drug reaction reports, it must be correlated with basic data concerning the incidence of the event in a representative population and data about the utilization of the drugs in that same population in order to develop a yardstick to measure the significance of adverse reaction reports. At present, the FDA is preparing four experimental programs designed to yield basic drug utilization data from selected patient population groups. These programs, dispersed in various geographical sections of the United States, are designed not only to supply the basic informa-

tion but to test the validity of data. These programs will be integrated into the national monitoring system, but each is directed toward different facets of the problem. Some of these systems have been developed under Public Health Service grants. Cooperation with the National Office of Health Statistics of the Public Health Service is also being explored to obtain medical parameters and drug utilization habits of the population at large.

The purpose of monitoring adverse reactions is to determine if there is a real relationship between the administration of a drug and the apparent resulting adverse reaction. If there is such a relationship, then the factors must be assembled with regard to the benefit-to-risk ratio of using this drug, taking into account other drugs currently available for treatment of the disease.

The ultimate result of the adverse reaction program is a regulatory decision by the Food and Drug Administration to permit the continued distribution of the drug under its present labeling or to undertake corrective action where necessary. The latter may consist of such steps as a request to revise the labeling to warn physicians of the possibility of the adverse reaction; issuance of a warning letter to physicians in addition to revised labeling; or in the most urgent cases, complete withdrawal of the drug from the market.

V. International Health Communications

While the programs and plans which have been described are primarily geared to domestic needs, it is clear that international needs are no less urgent or complex. The following quotation of former Surgeon General Terry demonstrates how the PHS and WHO might engage in joint actions to improve international biomedical communications:

> Possibilities for joint international action to improve medical communications have engaged a serious attention of the World Health Organization. Its Executive Board declared in January 1965 that "A World Health Research Center could make very important contributions toward the resolution of major world health problems, notably in epidemiology and in the analysis and handling of health and biomedical information." The Public Health Service has encouraged and supported this proposed activity of the WHO, but much remains to be done on a national basis if the Service is to be in an effective position for cooperating and providing leadership internationally in medical communications. For this, it seems most desirable to strengthen our resources for top-level planning and coordination, and provide support for those medical communication projects and demonstrations which are not unique to any one part of the Service but are basic to the total health program of the Nation and of the world. Such a policy must protect and conserve the initiative creativity, responsibilities, and authorities which are necessary for the effective prosecution of our categorical programs. At the same time, we must avoid unnecessary duplication in medical communications, expedite consistent approaches, and stimulate common agreements for the handling of biomedical information through improved intragency and interagency coordination, and a more intense effort to work with a non-Federal and international agencies and organizations.[259]

The Surgeon General's Conference on Health Communications emphasized the importance of U.S. participation in international health communications activities:

> It is important, in accordance with the basic policy of our country, to cooperate with other countries in health matters. One of the most important things the United States can export, particularly to developing countries, is health informa-

[259] In hearings before the Subcommittee on Labor and Health, Education, and Welfare Appropriations of the House Appropriations Committee, 1965, pt. 2, p. 22.

tion. In turn, the United States can benefit, as will others, from worldwide interchange of health information.[260]

VI. Findings and Recommendations

The scope of problems in health communications and the expanded efforts which the Department of Health, Education, and Welfare must launch to solve them makes the form of current and planned organizational assignment of health communications responsibilities a proper matter for concern. The current assignment of responsibilities within the Department for health communications is inadequate. Responsibility for this important function should be focused in one organization at both departmental and agency levels. With its comprehensive service and central role in biomedical communications, the subcommittee feels the National Library of Medicine should be the primary central focus for such activities both within the Public Health Service and within the Department of HEW. In addition, the NLM should be given responsibility for coordinating the health information activities of the Department with related activities of other Federal agencies and institutions.

In order to enable the NLM to carry out such expanded assignments effectively, it would appear not only desirable but necessary to give the NLM, in its expanded role, a higher organizational status within the Department and to include it within the Department of Health recommended in part A of this report.

The National Library of Medicine currently performs two basic functions:

(*a*) Operation of the Nation's most comprehensive biomedical information resource; and

(*b*) Support of the nationwide biomedical library network (under the Medical Library Assistance Act of 1965) by providing financial assistance for—

1. Extending basic library resources,
2. Publications,
3. Technical manpower development,
4. Research,
5. Biomedical library construction,
6. Special scientific project, and
7. Development and operation of regional libraries.

In addition to these current activities, the subcommittee feels the National Library of Medicine should undertake additional functions. Specifically, it should:

A. Establish a research center in biomedical communications.—Establishment and operation of a center to vigorously investigate biomedical communications is a needed step. Both internal and extramural research could be directed from such an activity. The subcommittee feels that for economy and the advantages of integrating library operations, the National Library of Medicine might consider combining regional or branch library operations with establishment of such a center. This center should be near a strong area of medical science. The center should serve as a base for support of a continuing biomedical education program.

B. Establish a national biomedical information clearinghouse and referral service.—The National Library of Medicine should serve as a

[260] Surgeon General's Conference on Health Communications, Nov. 5–8, 1962, p. 9.

central switching unit between the many varied sources and users of biomedical information services offered. This should include identifying and supplying users with new types of educational resources, auxiliary types of publications, medical translations, and bibliographies. Other major services should direct users to correct sources of information materials such as specialized information centers, research and medical libraries, ongoing research and development, and new educational resources. Such a service should be closely related to current National Library of Medicine functions in the processing and servicing of requests for information.

C. Control the Medical Audiovisual Branch of the Communicable Disease Center.—The transfer of control of this branch from CDC should enable the NLM to integrate more closely audiovisual activities with other biomedical communication services.

D. Coordinate all health communications activities in the Public Health Service.—The National Library of Medicine through an expansion of its central role should serve as the principal arm of the Surgeon General in assuring that a consistent well-coordinated attack on the many problems of health communications is undertaken.

The current organization of the Public Health Service should be changed accordingly. Two suggested alternatives are:

1. Establish new organizational units under the National Library of Medicine and assign new functions to them (fig. 1); or
2. Establish a Bureau of Health Communications with all major functions organized as divisions of the Bureau (fig. 2).

The subcommittee supports the second alternative as a well-balanced organization which should be adopted by the Public Health Service. It would provide a Bureau Director responsible for coordinating all Public Health Service health communications activities and subordinate organizations responsible for major biomedical communications activities in research and development, extramural grant and contract support, audiovisual and library services.

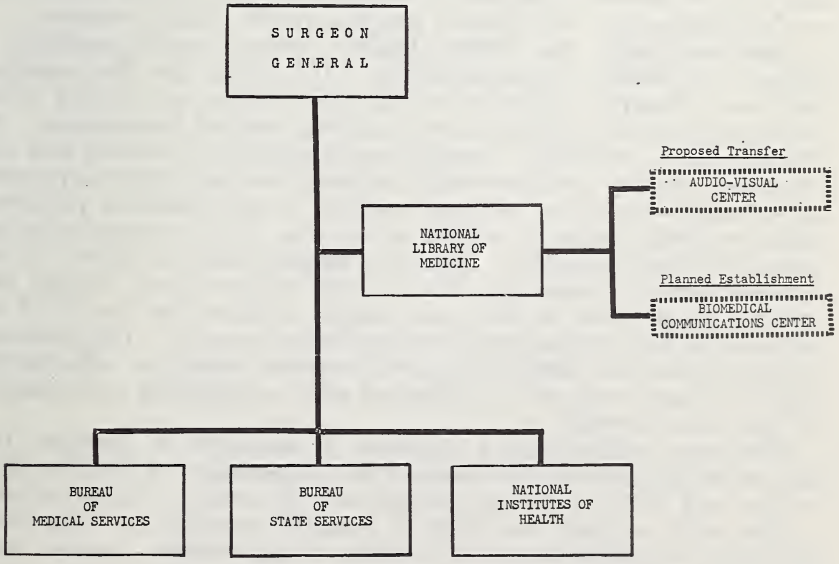


FIGURE 1

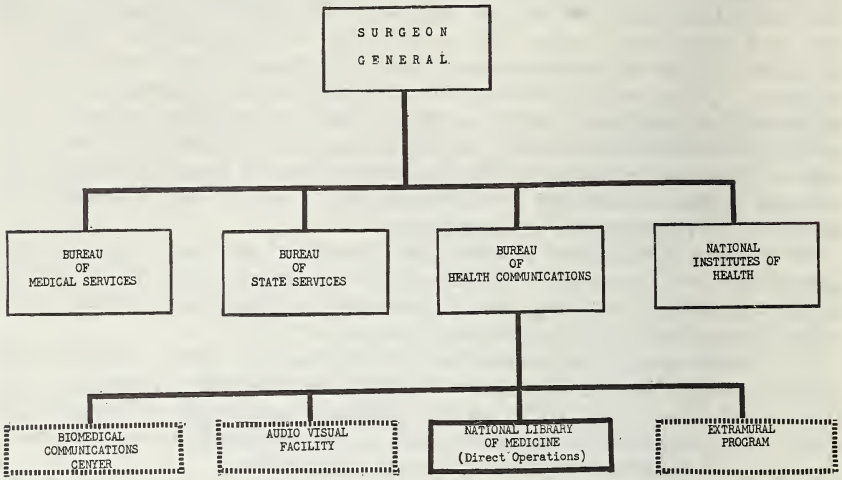


FIGURE 2

SUMMARY

The subcommittee believes that the National Library of Medicine which has demonstrated its capability to apply modern methods to handle the publications explosion should also be given the responsibility to organize and distribute other forms of information resources needed for research, teaching, and practice of medicine.

Particularly the subcommittee believes that audiovisual material generated by the PHS and specialized medical information services supported by PHS should be administratively and organizationally related to the NLM. This would assure the Nation of comprehensive and uniform access to the pool of medical knowledge which is essential to the development and further progress in the health sciences.

Organizationally, the Public Health Service should establish a Bureau of Health Communications. It should use the existing National Library of Medicine and the CDC audiovisual facility as its principal operating elements for supplying medical information. It should plan to establish a central communications research and development facility combined with a regional medical library to provide opportunities to solve national medical communications problems while rendering regional services to an area of the country with inadequate library facilities. This is in keeping with the intent of the Medical Library Assistance Act of 1965 which clearly defined the medical information problem and made provision for the NLM to serve as the hub of a national medical library network. The proposed reorganization and newly proposed programs would be reflected in improved care for the sick and disabled while contributing to the health of the Nation broadly.

Whatever administrative structure is employed to perform the biomedical information functions of the Department of Health, Education, and Welfare, certain obligations will persist. These include:

The duty to share the yields of research, whether by continuing education of practitioners, new systems of information transfer, promotion of public knowledge, support of group practice, or any com-

bination of methods, so as to apply the full power of modern science to the enhancement of health.

The duty to monitor health sciences and conditions by such means as the collection and analysis of data and documents so as to yield the information required by scientific investigators, administrators, legislators, editors, and scholars.

The duty to search for and develop methods of improving the acquisition and handling of biomedical information so as to lower costs, heighten accuracy, accelerate flow, minimize requirements, and maximize utility.

The duty to develop and maintain plans, programs, staff, system, facilities, and budgets sufficient to meet prospective needs of the Department in response to society's demands for biomedical information.

The information that goes to the medical profession is used for an exalted purpose—the preservation of life. It must, therefore, be the best information we have and it must be presented in the best possible manner.

APPENDIXES

Appendix A

Health Activities in Federal Agencies Other Than HEW

January 5, 1966.

Mr. Charles L. Schultze,
Director, Bureau of the Budget,
Executive Office Building, Washington, D.C.

Dear Mr. Schultze: In recognition of the need for continuing legislative oversight of the general field of health, the Committee on Interstate and Foreign Commerce has established a special subcommittee to study the organizational structure and health activities of the Department of Health, Education, and Welfare.

We are aware, of course, that Federal health activities are not confined to the Department of Health, Education, and Welfare. In order to place our study of HEW in proper focus, therefore, we must take into account the health activities of other agencies within the Federal government. Accordingly, I am writing to ask your assistance in this project.

It would be particularly helpful to the work of our subcommittee if you could supply us with a statement of the work and responsibilities of other government agencies in the field of public health and health-related activities. By health activities, I have primary reference to (a) the providing of health care, (b) the support, either directly or indirectly, of health-oriented biomedical research, and (c) the support of research in environmental health. We would also like to have a statement of the funds expended in support of these activities by the various agencies. This material will be of great assistance to us in placing the activities of HEW in the context of the entire Federal effort in the area of health.

Needless to say, the subcommittee would also welcome your personal views regarding the Federal health effort, and any ideas or suggestions you may have for more effective coordination of health activities among the Federal agencies involved.

The subcommittee may elect to make a committee print of these materials, and we want to be sure that we have stated correctly the health activities and responsibilities of the various Federal agencies. Because of the substantial time and effort necessarily involved, let me suggest that your staff contact Mr. Jonathan W. Sloat or Mr. Daniel J. Manelli of our staff at 225–4441 to arrange a suitable format and schedule for this material.

I want to assure you that your cooperation will be greatly appreciated.

With kindest regards, I am

Sincerely yours,

Paul G. Rogers,
Chairman, Subcommittee on HEW Investigation.

Executive Office of the President,
Bureau of the Budget,
Washington, D.C., March 29, 1966.

Hon. Paul G. Rogers,
Chairman, Subcommittee on HEW Investigation,
House of Representatives, Washington, D.C.

Dear Mr. Chairman: The enclosed reports on the health programs of Federal agencies have been prepared in response to your letter of January 5, 1966, and subsequent conversations with Mr. Daniel J. Manelli of your staff.

Enclosure A is a reprint of Special Analysis H, *Federal Health Programs*, from the Budget for Fiscal Year 1967. This special analysis provides a comprehensive summary of all Federal expenditures for medical and health related activities.

Enclosure B supplements Special Analysis H by providing a more detailed description of the major Federal health programs, and a statement of expenditures for the fiscal year 1965, 1966 and 1967.

Enclosure C lists the major interagency committees related to health activities, and reflects a part of the effort being made by Federal agencies to coordinate their activities.

I would also refer you to the President's Message on Health and Education of March 1, 1966. The Message recommends additional legislation to strengthen Federal health programs, indicates the need for reorganization of the health functions of the Department of Health, Education, and Welfare, and recommends legislation to improve the personnel system of the Public Health Service.

I would be pleased to provide your subcommittee any additional information which you might require.

Sincerely,

CHARLES L. SCHULTZE, *Director.*

Enclosure A

SPECIAL ANALYSIS H

FEDERAL HEALTH PROGRAMS

Reprint of Pages 102 to 112 From the Special Analysis,
Budget of the United States, 1967

Detail will not necessarily add to totals because of rounding

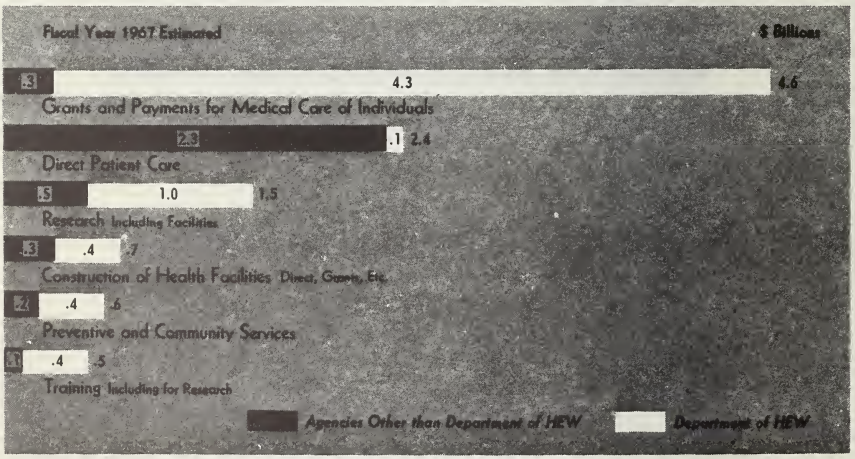
BUREAU OF THE BUDGET
January 1966

Special Analysis H

FEDERAL HEALTH PROGRAMS

This analysis provides a comprehensive summary of expenditures for all the medical and health-related activities of the Federal Government. It includes those activities classified in the "health" function as well as health programs included in other groupings. Government cash payments to the public in this broad category will rise to an estimated total of $10.3 billion in 1967. This total is derived from $7.8 billion expenditures from administrative budget accounts and $3.3 billion from trust funds, less interfund transfers of $0.8 billion. This spending will finance a wide variety of activities—hospital care and medical treatment in Federal and non-Federal facilities, construction of health facilities, health research and training, and a multitude of preventive and community health and health-related programs in Federal, State, and local governmental institutions and by private hospitals, research organizations, and individual practitioners. The expenditures from administrative budget funds continue to be the largest segment of health spending and they will account for 7% of total administrative budget spending. However, the program for hospital insurance and supplementary medical benefits for the aged under the social security system will be financed through trust funds which will account for 29% of health expenditures in 1967.

Federal Expenditures, *Medical and Health-Related Activities by Category*



Recent trends in Federal health-related expenditures.—Health programs are among the oldest activities of the Federal Government, some of them predating the Constitution. The earliest were for medical care of soldiers, merchant seamen, and veterans. Around the beginning of the present century, the Federal efforts in health research and consumer protection, such as those under the Pure Food and Drug Act, made their appearance. Following World War II, the directly operated patient care programs of the Defense Department and Veterans Administration overshadowed the other segments of Federal health expenditure. Since that time, while expenditures for these programs increased moderately, the role of the Federal Government shifted rapidly to one of large-scale grant support for health infrastructure—at first hospital and other facility construction, medical research, and State and local community services for specific disease categories or health problems, and, subsequently, health manpower, especially physicians, dentists, and nurses, and, provision of a full range of facilities and services for comprehensive care to individuals or for specific problems such as water pollution. Today, with hospital and supplementary health insurance for the aged through the social security system and medical assistance payments for aged and other needy through welfare grants, the Government role has moved toward assuring to all citizens the availability and accessibility of high quality medical care, regardless of income.

Although this special analysis has not existed long enough to provide a long-term series of data, comparable information is available for fiscal 1958. The figures provide some perspective on the sharp change taking place. In 1958, obligations for health activities totaled $3 billion, of which $1.9 billion were by the Defense Department and Veterans Administration, largely for patient care in Federal facilities. By 1967, total expenditures will have grown to $10.3 billion, and $3.3 billion of this spending will be for the new program of care of aged patients who, traditionally, have not been Federal beneficiaries. Thus, these expenditures for the social insurance medical programs will exceed in 1967 the total Federal spending for health in 1958.

Another important change from the situation in 1958, reflecting the changing content of the Federal Government's health role, is the relative portion of the Federal health budget which is managed by the Department of Health, Education, and Welfare. In 1958, the programs of Health, Education, and Welfare accounted for $0.8 billion of the $3 billion Federal total. In 1966, the Department of Health, Education, and Welfare is expected to spend $3 billion, 48% of the total of $6.3 billion. Almost all of that spending is from administrative budget funds. In 1967, with the addition of the trust fund programs, HEW's total is expected to rise to $6.6 billion (adjusted for interfund transfers), 64% of the total.

Distribution of Federal health programs by agency.—Eight Cabinet departments and more than a dozen other agencies conduct or support health programs. In addition, every agency finances health programs for Federal employees. Many of the health activities of these agencies are not classified in the "health, labor, and welfare" function, but are carried on as part of programs for other purposes and are classified in the functional categories according to the basic purpose served, such

as "national defense," "veterans benefits and services," etc. However, because these activities contribute to advancing the Nation's health, they are included in this analysis. Thus, while the regular functional classification shows expenditures of $3.6 billion in 1967 for "health services and research"—all by the Department of Health, Education, and Welfare—the amounts included in this analysis are almost three times as large and cover many agencies. Table H–1 shows the expenditures for each agency.

As has been noted, 64% of all Federal budget and trust fund spending for health in 1967 will be by the Department of Health, Education, and Welfare. Spending by the Department of Defense is increasing by $223 million, due to the military situation in Vietnam and resultant increase in personnel strength of the armed services, and will account for 14% of the total. The Veterans Administration is estimated to account for another 14%. The bulk of the health expenditures by the Department of Defense and the Veterans Administration are for the provision of direct care and treatment, most of which is provided in their own hospitals and clinics. These two agencies also have sizable expenditures for health facilities, for training, and for support of health research.

The Department of Health, Education, and Welfare, on the other hand, spends only a comparatively small portion of its health funds to provide direct medical care in Federal facilities, principally for merchant seamen and Indians in Public Health Service hospitals. About half of the Department's expenditures, or $3.3 billion, will be from trust funds and will reflect the first substantial impact of the newly enacted program for health and medical care for older persons. The largest proportion of the Department's health care outlays from administrative budget funds continue to be for medical research and training and for grants to States and localities to cover medical expenses of public assistance recipients and assistance for medical care of the aged. The Department also spends substantial amounts through the Public Health Service for grants for construction of health facilities, for support of local and State community health, and for environmental health activities.

The remaining $870 million of the estimated expenditures in 1967 will be made by more than 20 other departments and agencies. Among these, the largest single amount is for the Department of Agriculture for research and for meat and poultry inspection. Significant expenditures are also made by the Agency for International Development and the Department of State which support health activities in other countries, the Atomic Energy Commission with its substantial biomedical research activities in the radiological field, the National Aeronautics and Space Administration with research activities in space medicine, and the National Science Foundation which underwrites basic research in biosciences. The newly organized Department of Housing and Urban Development makes advances and loans for water and sewer facilities, for neighborhood health centers, and other health facilities. The newly enacted programs supporting health facilities and the 1965 expansion of water and sewer facilities programs account for the more than threefold increase in the Department's expenditures from 1966 to 1967.

Distribution of Federal health expenditures by category and by beneficiary group.—Table H–2 shows the distribution of the total Federal medical and health-related expenditures for the 3 fiscal years, 1965–67, by six categories. The preceding chart on estimated expenditures for 1967 depicts the distribution of the outlays in each category between the Department of Health, Education, and Welfare and all other agencies.

Of the total expenditures of $10.3 billion in 1967 for medical and health-related purposes, $7 billion, or about 68%, will be for provision of health care either directly in Federal facilities or financed by Federal grants or payments for services by non-Federal facilities. This is an increase of $4.1 billion from 1965, $3.4 billion of which is the change from 1966 to 1967, mostly because of the trust-funded programs of medical care for older people. These social security medical programs are causing a reversal in the previously established ranking of the two largest categories. Whereas direct patient care was the largest category of expenditure through 1966, the onset of large expenditures for the new programs for the aged make the nondirect care category the largest in 1967.

The direct care expenditures amount to $2.4 billion, or 23%, of total expenditures. Most of this service is provided in hospitals of the Department of Defense, Veterans Administration, and the Department of Health, Education, and Welfare, which, in all, contain almost 10% of all hospital beds in the United States.

Table H–3 shows the number of hospitals, hospital beds, and the average daily number of patients during 1965–67. The number of individual patients during any year is, of course, many times the daily census because hospital stays average from 7 to 75 days for most agencies. In addition to this large number of inpatients, several million individuals each year receive outpatient care or treatment in the Federal facilities. The 1966 and 1967 increases shown in the data for the Department of Defense reflect increased military operations in Vietnam and supporting activities.

Over one-sixth of the population in the United States is potentially eligible for direct hospital care or medical treatment in Federal facilities. Approximately 22 million living war veterans, including some 2 million with service-connected disabilities, comprise the largest single group of eligibles, although for ailments not related to military service hospital care is provided only to the extent that the veteran certifies that he is unable to pay for his care in private facilities. Active duty and retired uniformed service personnel numbering 3.2 million and their 5.6 million dependents are also covered. Approximately 2.5 million Federal employees are entitled to treatment for in-line-of-duty disabilities, although such injuries are comparatively infrequent. Other eligible groups include 380,000 American Indians and natives of Alaska, 118,000 American seamen, 21,500 inmates of Federal prisons, and civilians in the Panama Canal Zone, narcotics addicts, and patients with leprosy.

The second category of expenditures, which will become the largest in 1967 and reach $4.6 billion, or almost 45% of the total, is for grants and payments for hospital and health care in non-Federal facilities. Hospital insurance and supplementary medical benefits for the aged through social security accounts for 72% and grants by the Department of Health, Education, and Welfare for medical care

through public assistance continue to rise. During 1967, an estimated 19 million persons will be eligible although about 4.4 million are expected to receive benefits from the hospital insurance program and about 4.1 million from medical insurance. Medical cost for about 860,000 aged will be met through the spatial Federal-State program of medical assistance for the aged.

Under arrangements managed by the Civil Service Commission, health benefits are provided to over 2 million Federal civilian employees (90% of those eligible), and to 4.7 million of their dependents under the Federal Employees' Health Benefits Act. A similar program provides benefits for 227,000 retired Federal employees and their dependents. These payments are made from trust revolving funds into which are deposited both agency and employee contributions. Since the health benefits funds are revolving funds, with receipts offsetting expenditures, only the net effect of these transactions in the trust funds is included in the expenditures for this category. The Government's contributions, amounting to $165 million in 1965, $169 million in 1966, and $174 million in 1967, are included in the administrative budget figures and are mostly classified in this category. Also included in this category are payments for care of Federal beneficiaries, principally by the Veterans Administration and the Department of Defense in those cases where Federal facilities are not available.

Of general benefit to the entire Nation are the infrastructure activities of the Federal Government such as health research, training, and health construction assistance, and the preventive and community services, all of which are discussed separately in following paragraphs. Expenditures for these activities will total $3.3 billion in 1967, an increase of $1.1 billion from 1965. These categories account for almost 21% of the increase over 1965 in total health outlays. The amount of increases over 1965 is greatest for health research and facilities ($408 million), but the other categories will have higher rates of increase: Training (72%), preventive and community service activities (52%), and construction of health facilities (49%). Much of the increase in these programs reflects legislation enacted by the 88th and 89th Congresses for assistance to schools and to students in medicine, dentistry, and other health professions, for programs to combat mental retardation and promote mental health, for regional medical programs to combat heart disease, cancer, and stroke, and for increased Federal efforts for pollution control. Other expanding areas include activities relating to pesticides, community health, and foods and drugs.

About 73% of the $1.4 billion in Federal expenditures for health-related research and research facilities are by the Department of Health, Education, and Welfare, particularly the National Institutes of Health, which alone account for $815 million. The Department of Defense, the Atomic Energy Commission, the National Science Foundation, and the National Aeronautics and Space Administration also make sizable outlays for health research.

Training, including training for research, accounts for $546 million in 1967 expenditures. Again, the Public Health Service, and especially the National Institutes of Health, is the major source, although the Department of Defense also spends significant amounts.

Of the $635 million for preventive and community health services, $247 million will be spent by the Public Health Service, the Food and

Drug Administration, and the Children's Bureau, all agencies of the Department of Health, Education, and Welfare. The Federal Government's programs of assistance to underdeveloped countries are also responsible for about $100 million of the outlays and the Department of Agriculture programs account for most of the remainder.

The Hill-Burton hospital construction program accounts for $233 million out of $672 million to be spent in 1967 for construction of facilities other than for research. The Veterans Administration's expenditures of $68 million represent the seventh year of that agency's 15-year hospital replacement and modernization program. The Department of Defense will also spend $115 million for construction.

Proposed legislation.—Legislation to fill significant gaps in Federal health programs has been proposed by the President. The 1967 budget includes net new obligational authority of $94 million and net expenditures of $26 million for the following items: (1) $23 million in estimated expenditures for a new Federal-State partnership in health service programs, systems-oriented studies of the organization and delivery of medical care services, planning for accelerated modernization of obsolete hospital and health care facilities, training of medical technologists and allied health professionals, and the improvement of Federal health organization and career development; (2) $24 million for the control of environmental pollution through the demonstration of water pollution control in selected river basins, increased research and development and increased training in pollution sciences, and improved water pollution enforcement authority; and (3) estimated savings of $21 million in expenditures from the conversion of existing direct Federal loans to medical and nursing students to a system of loan guarantees with interest subsidy.

Table H–1. **FEDERAL EXPENDITURES FOR MEDICAL AND HEALTH-RELATED PROGRAMS BY AGENCY** (in millions of dollars)

Agency	1965 actual	1966 estimate	1967 estimate
ADMINISTRATIVE BUDGET			
Department of Health, Education, and Welfare:			
Public Health Service:			
National Institutes of Health	779.8	1,000.0	1,150.0
Other	603.7	737.1	880.0
Water Pollution Control Administration	100.9	121.0	181.5
Welfare Administration	628.3	920.8	929.2
Social Security Administration	----------	37.0	844.0
Other	97.4	128.9	168.9
Total, Department of Health, Education, and Welfare	2,210.1	2,944.8	4,153.6
Veterans Administration	1,265.7	1,343.0	1,386.5
Department of Defense:			
Army	463.3	563.7	748.7
Navy	200.6	255.1	287.0
Air Force	400.7	414.3	420.2
Other	1.7	2.1	2.5
Total, Department of Defense	1,066.3	1,235.2	1,458.4

Table H-1. **FEDERAL EXPENDITURES FOR MEDICAL AND HEALTH-RELATED PROGRAMS BY AGENCY** (in millions of dollars)—Continued

Agency	1965 actual	1966 estimate	1967 estimate
ADMINISTRATIVE BUDGET—Continued			
Agency for International Development	50.6	60.0	92.0
Atomic Energy Commission	90.1	95.4	102.6
Department of Agriculture	114.2	122.5	128.2
National Aeronautics and Space Administration	50.6	79.1	75.6
Department of Housing and Urban Development	39.8	27.2	87.1
National Science Foundation	25.9	35.1	35.9
Civil Service Commission	27.0	29.2	31.7
Office of Economic Opportunity	5.6	39.0	74.9
Department of State	19.5	21.9	23.8
Department of Labor	17.8	17.8	20.3
Department of Justice	7.8	7.7	8.0
Peace Corps	5.9	7.2	7.5
Panama Canal	7.3	7.8	7.8
Small Business Administration	8.3	8.5	10.3
Department of the Interior	4.4	4.9	4.9
General Services Administration	1.9	0.7	----
United States Information Agency	0.4	0.4	0.4
Federal Aviation Agency	1.7	1.7	1.7
Military Assistance Program	15.0	15.0	20.0
Transitional grants to Alaska	0.9	0.3	----
Contributions by Federal agencies to Federal employees' health benefits funds not included above	126.7	127.6	129.1
Total net budget expenditures for health	5,163.5	6,232.0	7,860.3
Interfund transactions	----	−37.0	−844.0
TRUST FUNDS			
Department of Health, Education, and Welfare: Social Security Administration	----	105.0	3,305.0
Civil Service Commission, net	−10.0	8.6	−7.9
United States Soldiers' Home	6.9	7.4	8.5
Railroad Retirement Board	----	0.4	0.3
Total trust fund expenditures for health	−3.2	121.4	3,305.9
Total budget and trust fund expenditures for health	5,160.3	6,316.4	10,322.2

Table H-2. **FEDERAL EXPENDITURES FOR MEDICAL AND HEALTH-RELATED ACTIVITIES BY CATEGORY** (in millions of dollars)

Category	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	2,022.0	2,209.9	2,397.9
Federal grants and payments for hospital and health care in non-Federal facilities	913.8	1,374.9	4,623.1
Medical research, total	1,040.1	1,320.6	1,448.3
(a) Conduct of research	(965.5)	(1,214.2)	(1,235.1)
(b) Research facilities	(74.6)	(106.4)	(123.2)
Training, including training for research	316.9	448.9	546.1
Prevention and community services	417.6	493.7	634.5
Construction of hospitals and health facilities	449.9	468.4	672.3
Total expenditures from administrative budget and trust accounts	5,160.3	6,316.4	10,322.2

Table H-3. **FEDERAL HOSPITALS, OPERATING BEDS, AND PATIENT LOADS**

	1965 actual	1966 estimate	1967 estimate
Number of hospitals:			
Defense	225	230	233
Health, Education, and Welfare	66	64	64
Veterans Administration	171	166	167
Other	35	35	35
Total	497	495	499
Number of operating beds:			
Defense	39,677	46,842	61,858
Health, Education, and Welfare	15,822	15,307	15,220
Veterans Administration	119,326	118,664	120,034
(Nursing home beds included in total)	(208)	(1,645)	(3,000)
Other	3,159	3,159	3,159
Total	177,984	183,972	200,271
Average daily patient load:			
Defense	29,376	35,844	48,150
Health, Education, and Welfare	13,226	12,892	12,687
Veterans Administration	109,333	109,710	111,147
(Nursing home beds included in total)	(150)	(1,510)	(2,790)
Other	2,055	2,119	2,144
Total	153,990	160,565	174,128

Table H-4. **FEDERAL EXPENDITURES FOR MEDICAL AND HEALTH-RELATED PROGRAMS** (in millions of dollars)

Agency and program	Functional code	1965 actual	1966 estimate	1967 estimate
ADMINISTRATIVE BUDGET FUNDS				
National defense:				
Department of Defense:				
Hospital and medical care of military personnel and their dependents, retired personnel and their families on a space available basis, and civilian employees and their dependents overseas	051	880.2	1,011.3	1,156.0
Research in preventive medicine, improved methods of caring for and rehabilitating the sick and injured, and studies relating to medical problems of military science	051	98.4	108.4	118.5
Professional and technical training of personnel	051	56.6	67.1	69.3
Construction of hospitals and medical facilities	051	31.1	48.4	114.6
Department of Health, Education, and Welfare: Stockpiling of medical supplies	059	12.6	10.0	10.0
Atomic Energy Commission: Research on the effects and use of radiation	058	89.3	94.6	101.7
Total, national defense		1,168.2	1,339.8	1,570.1

Table H-4. **FEDERAL EXPENDITURES FOR MEDICAL AND HEALTH-RELATED PROGRAMS (in millions of dollars)—Continued**

Agency and program	Functional code	1965 actual	1966 estimate	1967 estimate
ADMINISTRATIVE BUDGET FUNDS—Continued				
International affairs and finance:				
Peace Corps: Assistance to underdeveloped countries particularly for nursing and malaria eradication projects	152	5.9	7.2	7.5
United States Information Agency: Medical care of Foreign Service officers who become ill abroad	153	0.4	0.4	0.4
Agency for International Development: Grants, loans, and other assistance to underdeveloped countries in meeting their most pressing health problems	152	50.6	60.0	92.0
Department of State:				
Contributions to international organizations, conferences, and medical and hospital care of Foreign Service personnel and their dependents	151	18.0	20.2	21.9
Assistance to refugees from Communist countries, except Cuba	152	0.5	0.7	1.0
Mutual educational and cultural exchange activities	153	1.0	1.0	0.9
Military assistance program: Medical personnel and construction	-----	15.0	15.0	20.0
Total, international affairs and finance	-----	91.4	104.5	143.7
Space research and technology:				
National Aeronautics and Space Administration: Research on health factors and human capabilities in advanced aerospace systems	251	50.6	79.1	75.6
Agriculture and agricultural resources:				
Department of Agriculture: Plant and animal research; meat and poultry inspections	355	114.2	122.5	128.2
Natural resources:				
Department of the Interior: Care of Aleut Indians in Pribilof Island, Alaska, and grant to territories and American Samoa	910	4.1	4.6	4.6
Commerce and transportation:				
Small Business Administration: Loans for construction and operation of nursing homes and other health-related facilities	506	8.3	8.5	10.3
Department of Housing and Urban Affairs:				
Advances and loans to local communities for construction of sewer, water, and other health-related facilities, and grants for urban services and community facilities	553	39.8	27.2	87.1

Table H-4. **FEDERAL EXPENDITURES FOR MEDICAL AND HEALTH-RELATED PROGRAMS** (in millions of dollars)—Continued

Agency and program	Functional code	1965 actual	1966 estimate	1967 estimate
ADMINISTRATIVE BUDGET FUNDS—Continued				
Health, labor, and welfare:				
Department of Health, Education, and Welfare:				
Freedmen's Hospital: Operation of a community teaching hospital serving Howard University Medical School	651	3.9	4.5	4.9
St. Elizabeths Hospital: Hospital care for the mentally ill in the District of Columbia	651	9.9	12.8	10.5
Public Health Service:				
Health services for Indians	651	62.2	66.7	72.5
Construction of Indian health facilities	651	9.2	8.0	14.0
Medical care of merchant seamen, narcotic addicts, and other Public Health Service beneficiaries	651	54.5	58.0	61.0
Quarantine activities	651	6.9	7.5	7.9
Grants and loans for construction of hospital and health facilities	651	200.5	205.6	257.6
Support of medical, dental, and nursing education and training	651	31.9	80.5	127.2
Accident and disease prevention and control	651	197.3	255.3	322.4
Proposed legislation: Support for planning health facilities and services, and for modernization of obsolete medical facilities; conversion of student loans to guaranteed loans	----	----	----	2.1
Scientific activities overseas	651	3.9	5.0	12.0
Construction of health facilities	651	16.5	25.0	23.0
Environmental health activities	651	52.1	67.3	83.7
National Institutes of Health:				
Research	651	587.3	749.2	815.0
Training	651	145.6	195.2	217.7
Water Pollution Control Administration	651	100.9	121.0	158.0
Proposed legislation: Clean river demonstration projects and expanded research and training	----	----	----	23.5
Welfare Administration:				
Grants for maternal and child welfare	651	72.1	142.4	164.2
Assistance to refugees and repatriated U.S. nationals	653	2.1	3.5	5.6
Public assistance grants for hospital and health care	653	554.0	775.0	759.4
Vocational Rehabilitation Administration: Rehabilitation grants and research and training in problems of handicapped individuals	659	38.9	56.2	80.6
Social Security Administration: General fund payments to trust fund	654	----	37.0	844.0
Food and Drug Administration: Enforcement of the pure food and drug laws	651	40.6	51.1	64.9
Department of Labor: Accident prevention and administration of Federal employees workmen's compensation program	652	6.8	6.9	7.3
Department of the Interior: Health research related to mine operation	652	0.3	0.3	0.3
Office of Economic Opportunity	655	5.6	39.0	74.9
Total, health, labor, and welfare		2,203.0	2,973.0	4,214.2

Table H–4. **FEDERAL EXPENDITURES FOR MEDICAL AND HEALTH-RELATED PROGRAMS (in millions of dollars)—Continued**

Agency and program	Functional code	1965 actual	1966 estimate	1967 estimate
ADMINISTRATIVE BUDGET FUNDS—Continued				
Education:				
Department of Health, Education, and Welfare:				
Practical nurse training	704	4.9	4.9	5.0
Defense educational activities	702	3.1	3.9	7.8
National Science Foundation: Support of basic research in health-related fields	703	25.9	35.1	35.9
Total, education		33.9	43.9	48.7
Veterans benefits and services:				
Veterans Administration: Hospital, domiciliary, and outpatient care of veterans including medical research and construction and modernization of facilities	804	1,265.7	1,343.0	1,386.5
General government:				
Department of Labor: Hospital and medical care for Federal employees injured in line of duty	906	11.0	10.9	13.0
Federal Aviation Agency: Research	501	1.7	1.7	1.7
Department of Justice: Medical care of prisoners	908	7.8	7.7	8.0
Civil Service Commission: Government contribution to Federal employees' health benefit funds for retired employees and annuitants	906	27.0	29.2	31.7
General Services Administration: Matching grant for a hospital in southeast Washington, D.C.	905	1.9	0.7	----------
Panama Canal: Medical and hospital care for civilian and military personnel, sanitation and quarantine	910	7.3	7.8	7.8
Transitional grants to Alaska	910	0.9	0.3	----------
Total, general government	-----	57.6	58.3	62.2
Contributions by Federal agencies to employees' health benefits fund not included above	-----	126.7	127.6	129.1
Total net administrative budget expenditures for health	-----	5,163.5	6,232.0	7,860.3
Interfund transactions	-----	----------	−37.0	−844.0
TRUST FUNDS				
Civil Service Commission (revolving funds): Expenditures for employee health benefits	654	482.0	554.3	593.9
Receipts from employee and Government contributions	-----	−492.1	−545.7	−601.8
Net expenditures from trusts revolving funds	-----	−10.1	8.6	−7.9
Department of Health, Education, and Welfare: Social Security Administration: Expenditures for hospital and supplementary medical insurance	654	----------	105.0	3,305.0
United States Soldiers Home: Hospital and domiciliary care of retired and disabled enlisted personnel of the Regular Army and Air Force	805	6.9	7.4	8.5
Railroad Retirement Board	-----	----------	0.4	0.3
Total net trust fund expenditures for health	-----	−3.2	121.4	3,305.9
Total budget and trust fund expenditures for health	-----	5,160.3	6,316.4	10,322.2

Enclosure B

Department of Agriculture

The Department of Agriculture in pursuit of its responsibility to "acquire and diffuse among the people . . . useful information on subjects connected with agriculture in the most general and comprehensive sense of the word," carries out three major types of activity which have a direct effect on human health: scientific research, prevention, control, and eradication programs, inspection, and educational services.

The scientific research activities of the Department are carried out in 16 divisions of the Agriculture Research Service, the Consumer and Marketing Service and the Economic Research Service. These diverse activities are aimed at the following purposes: (1) learning how the infectious diseases and parasites of domestic animals are transmitted to man and developing methods for diagnosis, prevention, or control—some 90 domestic livestock diseases are transmissible to man; (2) learning about the toxicological effects of agricultural chemicals in animal and human food chains; (3) improvement of plants that yield steroid chemicals for making cortisone and related drugs—drugs which are preventing and ameliorating the effects of old-age diseases; (4) understanding the biology, ecology, and prevalence of insects affecting man and animals and their role as vectors of disease; (5) establishing the physiological availability of nutrients in foods—a departmental activity since 1893; (6) studying the metabolic responses of humans to different dietary combinations; (7) surveying the diets of population groups and determining their nutritive value; (8) maintaining a culture collection for identification and screening of microorganisms for the production of antibiotics and vitamins—the development of penicillin came from Department research in the microorganisms field; (9) developing dairy plant methods for removing strontium 90 from milk; (10) making statistical analyses of health care expenditures by farm families and special field studies on rural health—in cooperation with State experiment stations.

Other activities include (1) eradication of diseases such as brucellosis and tuberculosis—transmissible to man; (2) quarantine services to prevent introduction of animal diseases from foreign countries which may affect man; and (3) the regulation of pesticides—over 3,974 new products were registered last year and more than 2,231 official samples of economic poisons were analyzed and tested. A program to monitor the effects of agricultural pesticides on the environment was initiated in fiscal 1964 and expanded in 1965. By the end of 1965, 3,700 samples of soil, sediment, water, crops, fish, and other environmental media had been collected and analyzed.

The inspection of all meat and meat products moving in interstate and foreign commerce is compulsory under the Federal Meat Inspection Act. In fiscal year 1965 the Meat Inspection Division of the Department's Consumer and Marketing Service examined the production of 1,775 establishments located in 743 cities and towns. The inspection of poultry moving in interstate and foreign commerce is compulsory under the Poultry Products Inspection Act of 1957. In fiscal year 1965, 11.3 billion pounds of poultry products were inspected in over 900 plants.

The Cooperative Extension Service of the Department and the land-grant universities through its more than 15,000 agents located in almost every county of the Nation assists in meeting educational needs, including the needs of youth through the 4–H program. This program is supported jointly by Federal, State, and local governments and interested groups. Through these agents, technical information is made available on health hazards of pesticides, food preservation, meal planning and preparation, home sanitation, and other health problems.

These activities of the Department are coordinated with HEW through eight major interagency committees including the Federal Pest Control Review Board, Interdepartmental Committee on Community Air Pollution, and the Interagency Committee on Nutrition and Education. Joint projects include activities such as prevention of radioactive contamination of milk and research to identify, collect, and isolate cancer-retarding plant materials; and cooperation on enforcement efforts especially in the registration of agricultural pesticides.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Medical research:			
Conduct of research	37.1	39.6	38.0
Research facilities	1.0	0.4	2.7
Preventive and community services	76.2	82.5	87.5
Total	114.2	122.5	128.2

Atomic Energy Commission

Medical and health-related activities of the Atomic Energy Commission arise mainly in connection with its research program and its protective activities. By far the largest part of the research program is in the Division of Biology and Medicine; smaller health-related activities are carried out in the reactor development program.

Aside from small amounts paid to overcome the annual deficit at the AEC-owned Los Alamos community hospital and for radiological and health physics fellowships, AEC's programs are entirely composed of basic and applied research on the effects and usage of radiation. Approximately 54 percent of this research is in the biological sciences, 31 percent in the medical sciences, with the balance in applied fields such as agriculture and radiation sanitary engineering.

In the biological sciences, AEC conducts research on the effects of radiation on plants and animals with interest ranging from total behavior to the specific behavior of certain systems and organs. In addition, AEC conducts fundamental research at the molecular and cellular level and on the study of radiation genetics.

AEC's program in the medical sciences is principally in the areas of comatic effects of radiation, combating the detrimental effects of radiation, and health physics. AEC also conducts cancer research and radiological environmental health, coordinating its activity with that of PHS, and generally providing the basic research backup for the national program in this area.

In carrying out these activities, HEW and AEC cooperate through (1) the Federal Radiation Council, and (2) the National Committee on Radiation Protection, a private organization which includes HEW and AEC as sponsoring institutions. Further, there are bilateral contracts and joint projects between the agencies, such as an AEC-National Cancer Institute cancer research effort on cocarcinogenesis conducted at AEC's Oak Ridge National Laboratory. Finally, there has been established a close professional relationship between AEC and PHS scientists at the senior staff level as well as at the scientific working level.

Funds for medical and health-related activities

[Fiscal years—In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	0.1	0.1	0.1
Medical research, total:			
(*a*) Conduct of research	80.0	86.2	90.8
(*b*) Research facilities	9.3	8.4	11.0
Training, including training for research	.8	.8	.8
Total	90.1	95.4	102.6

Civil Service Commission

As the personnel agency for the Federal Government, the Civil Service Commission has a concern for the health of civilian Federal employees.

As part of its general responsibilities in the recruitment of civilian employees and the administration of the personnel system, the Civil Service Commission

establishes and reviews physical standards for civilian jobs in the Government, sets professional standards for doctors and other health personnel to be employed in civilian positions, and supervises and adjudicates claims for retirement on account of disability. Also, the Commission, at the direction of the President, exercises leadership in the Government's occupational health program for Federal employees, advises agencies on services to be provided, and makes an annual report, with recommendations, on the effectiveness of the program.

In addition, the CSC administers two large health insurance programs—one for active employees and for former employees who retired after fiscal year 1960 and one for former employees who retired before or during fiscal 1960. Under the Federal Employees' Health Benefits Act of 1959, the Commission qualifies insurance carriers to participate in the program. The individual employee or annuitant is then given the opportunity to select among the health benefits carriers for an insurance plan and level of services designed to meet his particular needs. The Government will contribute a portion of the cost of such plan and deductions are made from employees' salaries or retirees' annuities for the remainder of the cost. The health benefits plans provide, under various options, hospital, medical, surgical, obstetrical, and other supplemental benefits. At present, there are four basic insurance plans in which over 2 million employees and over 200,000 annuitants are participating. About 90 percent of all eligible Federal employees are participating.

The second insurance program is designed for retired employees who were not eligible for enrollment under the act covering active employees. Retirees may enroll in a uniform governmentwide health benefits plan or may retain or purchase non-Government health insurance plans. In either case, the Government and the retiree share on a specified basis the cost of either option. The benefits are generally less liberal than those provided under the employees' plans. On June 30, 1965, there were 227,300 participants in this program and 214,000 are expected to be participating on June 30, 1967. The decrease is expected primarily because of deaths of annuitants.

The Government's contributions to Federal employees and annuitants health benefits plans shall not exceed 50 percent of such cost according to law. Recent experience has been that the Government contribution on an overall basis averages about 32.5 percent of the insurance cost and the participants contribute about 67.5 percent of the cost. The figures below cover funds from both sources.

Funds for medical and health-related activities [1]

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Federal grants and payments for hospital and health care in non-Federal facilities	165.3	169.1	173.6

[1] Administrative budget.

Department of Defense

The primary mission of the Department of Defense health program is the provision of medical care and services to military personnel and their dependents. The responsibility for these services rests with each of the three military departments.

It is estimated that in 1967 the Department of Defense will be responsible for the complete medical and dental care of approximately 3.1 million active duty military personnel as well as a more limited amount of care for about 4.3 million dependents and, on a space available basis, for about 2.4 million retired personnel and their dependents. This care will be provided in 95 Army, 27 Navy, and 111 Air Force hospitals and in other Federal and civilian institutions. It is estimated that 233 military hospitals will have an average daily patient load of 48,150 and that outpatient visits in Defense medical and dental facilities will average about 220,000 daily.

The Dependent's Medical Care Act also authorizes medical care at Government expense by private physicians in community hospitals for wives, children, and dependent husbands of personnel serving on active duty in the military and other uniformed services of the Federal Government. It is estimated that in

1967 the dependents' medicare program will provide for 1,576,800 patient days in community facilities. In addition, military personnel may utilize community hospitals for emergency services where military or other Government facilities are not available.

Largely in support of its medical care program, the DOD supports health research and training programs. The research efforts relate to (1) preventive medicine, (2) unique military health problems, and (3) improved patient treatment and care.

Likewise, the training effort relates largely to insuring an adequate supply of health skills in support of the medical care program.

In addition, there are certain health activities of the DOD which do not directly relate to patient care. These activities are in the area of preventive medicine and environmental health.

In carrying out these responsibilities, the DOD and HEW cooperate by: (1) cross-servicing of hospitalization and patient services on a reimbursable basis, including, for example, the Army's administration of the medicare program for dependents of PHS uniformed personnel; (2) membership on more than 20 interagency committees, boards, and panels; (3) DOD participation on 28 study sections of NIH in such areas as surgery, dental study, biochemistry, general medicine, pathology, pharmacology, and visual services; (4) joint sponsorship of activities such as the medical education for national defense (MEND) program and joint studies of areas of common interest such as the NIH-Navy study of respiratory diseases at Great Lakes Naval Training Center and Camp Lejeune; and (5) cooperating in many other diverse areas of common interest in medical and dental techniques, biometrics, epidemiology, pest control, pathology, medical supplies, and medical training materials and facilities.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	798.1	920.7	1,054.2
Federal grants and payments for hospital and health care in non-Federal facilities	82.1	90.6	101.8
Medical research: Conduct of research	98.4	108.4	118.5
Training, including training for research	56.6	67.1	69.3
Preventive and community services	5.1		
Construction of hospitals and health facilities	26.0	48.4	114.6
Total	1,066.3	1,235.2	1,458.4

Department of Health, Education, and Welfare

The Department of Health, Education, and Welfare, through the Public Health Service, Food and Drug Administration, Water Pollution Control Administration, Welfare Administration, Social Security Administration, Vocational Rehabilitation Administration, St. Elizabeths Hospital, and Freedmen's Hospital, has the major responsibility in the Federal Government for safeguarding and improving the health of the people of this country. The health functions of the Department fall into three major categories: health research; health and related consumer protection; and health and medical services.

The major health research activities of the Department and, for that matter of the Government, are primarily carried out through the National Institutes of Health. However, other parts of the Public Health Service, the Food and Drug Administration, the Water Pollution Control Administration, the Vocational Rehabilitation Administration, and St. Elizabeths Hospital carry out basic and applied health-related research in support of their operating responsibilities.

The National Institutes of Health, through nine Institutes and one Division, supports nearly two-thirds of national health research. The program operates primarily through grants to institutions and to individuals for support of research in the medical and health-related sciences and training of individuals to increase the research manpower in the medical sciences.

The grants and related fellowships are awarded by the Institutes on the basis of merit as determined by study sections and advisory councils composed of non-Government scientists.

The Institutes conduct research mostly on the Bethesda campus, largely within the mission of each of the categorical Institutes. This research is conducted on cancer, heart disease, mental illness, arthritis and metabolic diseases, etc.

The environmental and community health programs of the Public Health Service and the Water Pollution Control Administration utilize grant programs to support research. However, unlike NIH, a larger proportion of their research effort is conducted directly by the Government and a large share of the research is applied research.

The Food and Drug Administration, Vocational Rehabilitation Administration, and St. Elizabeths Hospital also have health-related research activities. Again, most of it is in support of their operating missions.

The health and related consumer protection activities of the Department are carried out by the Food and Drug Administration, the environmental health programs of the Public Health Service, and the Water Pollution Control Administration.

These programs have the mission of protecting man from injuries by his environment. The Food and Drug Administration enforces laws designed to protect the consumer against misbranded and adulterated foods, drugs, cosmetics, and therapeutic devices. PHS has similar responsibility to protect man against the health hazards resulting from water, air, radiation, occupation, and milk and food. The PHS programs are designed to prevent and control environmental hazards through support of research training grants, and technical assistance to State and local programs in this field. The Water Pollution Control Administration programs are directed toward the control of water pollution by comprehensive planning, construction of treatment works, research on water quality standards, and on methods of pollution control and technical assistance and financial support to State and local agencies. Both the water pollution and the air pollution programs have enforcement authority to prevent environmental contamination.

Various HEW programs help provide health service to many thousands of beneficiaries. Some of these services are provided directly to merchant seamen, Indians, and Alaskan natives, patients in St. Elizabeths Hospital, and, most recently, to Cuban refugees.

Of special importance is the hospital and medical insurance program for the aged—Medicare—enacted by the 89th Congress and effective July 1, 1966. Administered by the Social Security Administration and financed largely out of special Trust Funds, Medicare is designed to provide basic hospital insurance—including nursing home care, psychiatric hospital services, and home health services—to persons 65 years of age or older. This plan covers not only those eligible for social security or railroad retirement benefits (about 16.9 million people), but also some 2 million others. Medicare also incudes a voluntary supplementary insurance plan covering physicians and other medical services for which eligible persons 65 or older pay $3 per month matched equally by Federal funds. More than 85 percent of those eligible for this voluntary coverage have already signed up.

In addition to Medicare, the 89th Congress enacted an expanded and more comprehensive program of medical care for needy persons utilizing existing Federal grant-in-aid programs to the States. This program, effective January 1, 1966, is designed to help States expand care not only to the needy aged, but also to people receiving assistance under programs of aid to families with dependent children, the blind, the disabled, and (optionally) to the so-called "medically indigent." In order to receive Federal matching funds (up to 83 percent with no limit as to amount) to pay for medical services, States must develop a plan, approved by the Secretary of HEW, providing for the steady expansion of medical care for the needy so that by July 1, 1967, certain minimum specifications are met with regard to hospital, laboratory, X–ray, nursing home, and physicians services. By 1975, a fully comprehensive system of medical care for all needy persons would have to be established in each State.

Similarly, under the vocational rehabilitation program, grants are made to the States to support medical or health services provided to individuals undergoing rehabilitation under the State program.

Other grant programs, administered by HEW, such as TB and VD grants or grants for maternal and child health services and Hill-Burton hospital construction grants, help the States to provide resources, manpower, and facilities to carry out vital health services for its citizens. Finally, the Department also finances extensive training, demonstration, and technical services which supplement these State grants.

For administering the numerous health programs, HEW has established an extensive mechanism to coordinate its activities with other Federal agencies and outside groups. The statements of the other agencies give an indication of the numerous interagency committees which help to coordinate the activities of the various Federal health programs. In addition, extensive use is made by HEW of outside advisory committees to draw on a wide diversity of judgments and backgrounds in establishing program missions and goals and coordinating programs with those outside the Federal Government.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	101.0	106.4	109.9
Federal grants and payments for hospital and health care in non-Federal facilities	654.5	1,096.1	5,127.6
Medical research:			
Conduct of research	638.6	824.2	922.0
Research facilities	55.6	84.8	100.4
Training, including training for research	215.3	323.9	414.3
Preventive and community services	265.0	326.3	416.2
Construction of hospitals and health facilities	280.1	288.1	368.2
Total	2,210.1	3,049.8	7,458.6

Department of Housing and Urban Development

The Department of Housing and Urban Development has a number of grant, loan and loan guarantee programs which have a direct effect on the construction of certain health-related facilities. These are advances of funds for public works planning, college housing loans, loans for public facilities, grants for water and sewer facilities and a loan guarantee program for nursing homes.

The Housing Act of 1954, section 702, authorizes the Federal Government to provide advances to State and local public agencies in order to encourage them to prepare and maintain a current and adequate reserve of public works as well as to promote economy and efficiency in planning and building public works. These advances are repayable without interest when construction is started. Among the eligible public works which are customarily assisted under this program are sanitation and water facilities. Hospitals and similar public health facilities, including clinics, nursing homes and laboratories also are assisted. Of the total obligations for advances in fiscal year 1965 about 62 percent were for this purpose, or $13 million.

The college housing loan program is intended to assist institutions of higher education in providing housing and related facilities for students and faculty where such assistance is not otherwise available on equally favorable terms. This includes housing facilities for student nurses and interns, of which there were 6 projects at a cost of $6.7 million. Eight regular projects had related infirmary facilities in some form.

Public facility loans are made to municipalities and other political instrumentalities of States to finance basic public works for which there is an urgent need. Communities with a population of less than 50,000 persons are eligible (150,000 in economic development areas) under the basic program. Priority is given for the construction of water and sewer facilities and other public works in communities under 10,000. Water treatment and distribution systems and sewer collection and treatment systems are among the most common types of projects which have been given such loans. In the fiscal year 1965, about 90 percent of the total number of loans were for this type of project and were about $23 million in amount.

The Federal Housing Administration is authorized to insure up to 90 percent of the amount of mortgages on nursing homes. Administratively, the Department has established a minimum of 20 beds for eligibility and has also established minimum standards of basic safety and health requirements equal or greater than the standards established by the States for licensing. During fiscal year 1965, insured mortgages under this program provided for 7,399 additional beds for a cumulative total of 29,890.

Title VII of the Housing and Urban Development Act of 1965 authorized the Department to make grants to local public bodies to finance up to 50 percent of the cost of the constructing, expanding, enlarging, and improving basic water and sewer facilities (other than sewage treatment works as defined in the Federal Water Pollution Control Act). It is estimated that about 200 grants will be approved in 1966 and in 1967 for $100 million each year.

Title VII of the 1965 Act also authorizes the Department to make grants to local public bodies to finance up to 66⅔ percent (75 percent in economic development areas) of the cost of providing neighborhood facilities necessary for carrying out a program of health, recreational, social or similar community service. Priority is given to projects designed to benefit members of low income families or otherwise substantially further the objectives of a community action program under the Economic Opportunity Act of 1964. It is expected that 48 grants will be approved in 1966 for $12 million and 125 grants in 1967 for $25 million. In the absence of experience under the program, it is impossible to determine what proportion of the facilities will actually be used for health services.

In carrying out these activities, the Department of Housing and Urban Development cooperates with the Departments of HEW, Agriculture, and Commerce where there are related programs. For example, a common preliminary inquiry form has been developed for applicants under the Water and Sewer Facilities Grant program and related ones of these Departments. In addition, it is the practice of the Department to refer all applications for loans involving health and sanitary facilities to HEW for comment, as well as obtaining certifications that sewage disposal facilities will provide for adequate treatment of waste materials before being discharged into public waterways.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Construction of hospitals and helath facilities	39.8	27.2	87.1

Department of the Interior

Health-related activities of the Department of the Interior are primarily related to health and safety factors in mines. However, activities in the Geological Survey, Bureau of Sport Fisheries and Wildlife, Bureau of Commercial Fisheries, and the Office of Territories are health-related.

The Bureau of Mines health research program is concerned primarily with workers in the mineral industries. The program consists of (1) research on dust and approval and testing of drill dust collectors, (2) respirator approval testing and research, (3) environmental surveys in metal mines, and (4) health and safety inspections in metal and nonmetallic mines.

The Geological Survey, as a byproduct of projects that investigate the quality of the Nation's surface and ground-water resources, compiles and analyzes data on the occurrence and distribution of elements in water that are, or may be, health-related. Other projects investigate the behavior of pollutants, including radioactive wastes, which are released into the soil-moisture environment of natural water systems, compile radiometric data, and study the variations of plants and soil composition under changing environments for the purpose of correlating these factors with the incidence of certain human diseases or other health problems and to determine the effects on other biological systems.

The Bureau of Commercial Fisheries conducts a research program to determine the possible uses, including health uses, of selected fish oils and to determine the nutritional value of certain fishery products. In addition, the Bureau reimburses the Public Health Service for the cost of medical and dental services furnished the residents of the Pribilof Islands. Grants are made to American Samoa and the Trust Territory of the Pacific Islands for the operation of the local government. Part of these funds is used for general public health purposes and the operation of hospitals and dispensaries.

Health-related activities of the Bureau of Sport Fisheries and Wildlife are limited to the indirect benefits resulting from suppression of rabies among wild animals and reduction of rodent filth in grain intended for human consumption.

The major committees in the health area to which both Interior and HEW belong include: Interdepartmental Committee on Water Resources, the Committee on Water Research of the Federal Council for Science and Technology, and the Technology Advisory Committee for the Uranium Mines Study.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	0.1	0.1	0.1
Federal grants and payments for hospital and health care in non-Federal facilities	3.7	3.7	3.7
Medical research: Conduct of research	.3	.3	.3
Construction of hospitals and health facilities	.4	.9	.9
Total	4.4	4.9	4.9

Department of Justice

The Bureau of Prisons provides an extensive health system for the medical and mental treatment of approximately 21,500 Federal prisoners. This service is operated and staffed by Public Health Service personnel with assistance from Bureau of Prisons staff and from inmates.

Facilities range from the Medical Center for Federal Prisoners at Springfield, Mo., through accredited hospitals at 15 other prison institutions to very limited services, operated by medical and technical assistants, at the remaining institutions. In-house capacity is augmented, where necessary, by use of private-medical resources on a contract basis. Funds for construction of a new psychiatric prison hospital, to be located at Butner, N.C., have been approved by the Congress.

Anticipated patient load for 1967 is estimated to be 391,000 patient-days and over 1 million outpatient treatments.

The physical and mental health activities in the Federal prison system are a major part of Prisons' efforts to rehabilitate its inmates. Special efforts are required to correct deficiencies in the physical condition of incoming prisoners (e.g., dental deterioration) and in mental rehabilitation.

Close working relationships exist between the Bureau of Prisons and the Department of Health, Education, and Welfare through the use of PHS medical and technical staffs for Prisons' hospital system and the use of PHS facilities where more advanced or complex treatment is required. Inmates at Federal prisons participate, on a voluntary basis, in various HEW medical research products. The Bureau of Prisons is also a member of the Interagency Committee on Narcotics.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	7.0	7.3	7.6
Construction of hospitals and health facilities	.6	.4	.4
Total	7.6	7.7	8.0

Department of Labor

Activities of the Department of Labor which may be considered health-related are concerned primarily with accidents to workers employed by the Government and in various industries.

The Federal Employees' Compensation Act authorizes medical and hospital expenses to be paid for Federal employees injured or contracting disease in the performance of their duty. During fiscal year 1965 a total of 150,401 payments were made on behalf of approximately 109,000 employees. It is anticipated that the 1967 experience will be about the same.

Under the terms of the Longshoremen's and Harbor Workers' Compensation Act, the Department of Labor directs the vocational rehabilitation of permanently disabled longshoremen. This is done in cooperation with, and mostly through, the facilities of the States' vocational rehabilitation system.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	1.2	1.4	1.3
Federal grants and payments for hospital and health care in non-Federal facilities	9.8	9.6	11.7
Training, including training for research	.3	.3	.3
Preventive and community services	6.4	6.5	7.0
Total	17.8	17.8	20.3

National Aeronautics and Space Administration

National Aeronautics and Space Administration medical and health-related projects are all in the research area related to space activities. Specifically, they are concerned with aerospace medicine, human factors research, biosciences, and the biological satellite flight program.

The objectives of the first two activities are: (1) To obtain a better understanding of man's capabilities and limitations and to determine his utilization in advanced aerospace systems, (2) to determine design requirements for equipment and subsystems which will guarantee an environment adequate for maintaining the high operating efficiency of crews during programed and emergency phases of advanced aerospace missions, (3) to determine overall human requirements and integrate them into the design of advanced aeronautical, astronautical, and ground support systems, and (4) to provide operational medical support to space flight missions and to conduct development and testing of systems and components to insure the effective performance and safety of the astronauts in flight and on the ground.

The bioscience program is being developed to provide this country with biological knowledge that can be gained only in the environment of space, and with the basic biological knowledge pertinent to space exploration and operations. Research is being conducted and planned on matters such as the detection and study of extraterrestrial life and its impact on evolutionary theories, and the effects of the space environments on the behavior and functioning of living organisms.

The objectives of the biosatellite flight project are to investigate the biological effects of decreased gravity and weightlessness, and the effects on biological rhythms of removal from the earth's rotation.

NASA conducts some research in its own facilities but also contracts with industry, finances research by other Government agencies, and awards research grants to universities in support of medical and health-related research.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Medical research: Conduct of research	50.6	79.1	75.6

National Science Foundation

The National Science Foundation, as part of its statutory responsibility to initiate and support basic research in all fields of science through grants primarily to colleges and universities, finances a significant volume of research in the life sciences, amounting to $57.5 million in the 1967 budget. That portion of the Foundation's activity in the life sciences which is considered to be particularly germane to the medical and health-related fields, will amount to an estimated $35.8 million in 1967. These expenditures support basic investigations in such scientific disciplines as molecular biology, genetics, developmental biology and metabolic biology.

Proposed project applications must pass a review, involving the use of panels of consultants who are experts in the field in which grants are requested. The NSF grant programs are administered with an awareness of the activities of other agencies in the support of research, so as to avoid duplication of effort in the support of specific research proposals and to assist in achieving balance in the support of basic sciences. This is particularly true of NSF's relations with NIH where the two agencies have cross-representation on each other's grant reviewing bodies and exchange information on grant applications.

In addition to supporting the conduct of research and facilities related to health, the Foundation also assists in the support of science education, including fellowships. It is expected that about $2.7 million of the funds budgeted for these purposes in fiscal year 1967 will involve the support of medical and health-related activities.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Medical research:			
Conduct of research	20.8	30.0	30.4
Research facilities	5.0	5.0	5.4
Training, including training for research	.1	.1	.1
Total	25.9	35.1	35.9

Office of Economic Opportunity

The Office of Economic Opportunity provides health and health related program services through the Job Corps and the Community Action Program.

The Job Corps provides complete health services to all the enrollees in the program. Initial medical examinations are provided in the youth's home town, sometimes under contract with a Veterans Administration or Public Health Service Installation and sometimes through contracts with private physicians. Once at a Job Corps center each youth is given complete dental and medical treatment. At the larger centers, this care is provided through hospital facilities and physicians at the center, while at the smaller centers it is done under contract with public or private agencies and physicians.

Community Action Program grants finance a variety of medical and health related activities. Project Head Start provides diagnoses and treatment for the more than ½ million children involved in the program each year. Research and demonstration projects have been funded covering such areas as (1) neighborhood health centers providing free services to the residents of urban slum areas, or (2) home health aides to provide care for elderly or incapacitated persons unable to avail themselves of regular public health services. Most of the Community Action health services are provided under programs developed by local Community Action agencies and designed to meet the particular health needs of the poor in the community in question. Wherever possible, such programs are developed with the cooperation and support of local public and private health agencies, and they are often operated by such agencies under reimbursement from Community Action funds.

[In thousands of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Federal grants and payments for hospital and health care in non-Federal facilities	3,720	22,725	39,538
Training, including training for research		7,000	9,000
Preventive and community services	1,900	9,300	26,380
Total	5,620	39,025	74,918

Small Business Administration

The business loan program of the Small Business Administration is intended to help small businesses obtain adequate financing on reasonable terms. Privately owned hospitals, convalescent and nursing homes, and medical and dental laboratories which are operated for profit are eligible for these loans which can be used for expansion, improvement, and general operations. Eligibility is restricted to—

(*a*) Hospitals with a capacity of less than 100 beds at the time of application;

(*b*) Convalescent or nursing homes with annual dollar volume of receipts of not more than $1 million; and

(*c*) Medical or dental laboratories operating in connection with an eligible proprietary hospital or, if independent, with an annual dollar volume of receipts of not more than $1 million.

In addition, private physicians may also qualify for these loans in connection with their practice of medicine. In fiscal year 1965, loans were made to 80 physicians and surgeons, 147 dentist and dental surgeons, 24 osteopathic physicians and chiropractors, 21 medical or dental laboratories, 9 hospitals, 65 sanatoriums and convalescent rest homes, and 31 other health service businesses, for a total of $8.3 million.

These loans may not be made for an amount exceeding $350,000 or for a term longer than 10 years.

The SBA is a member of the Subcommittee on Nursing Homes of the President's Council on Aging. This Subcommittee is chaired by HEW.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Construction of hospitals and health facilities	8.3	8.5	10.3

Department of State

The health-related activities of the Department of State, including the Agency for International Development and the Peace Corps, are part of the international activities of these agencies. These activities are carried on through (1) bilateral programs arranged directly between the United States and the governments of countries participating in foreign assistance and (2) various international organizations and other multilateral arrangements in which the United States is a participant.

International organizations with health programs, such as the World Health Organization and the Pan American Health Organization, benefit from U.S. support in the form of assessed annual contributions financed by the State Department and voluntary contributions financed by AID. These organizations carry on a variety of health, sanitation, and nutrition programs, ranging from a limited medical research activity carried on by the WHO to a large malaria eradication program conducted under the auspices of WHO, PAHO, and UNICEF.

Department of State assistance to escapees from Communist countries includes the provision of necessary medical care. These programs are carried out through contracts with voluntary agencies. In certain instances, such as the flow of refugees to Hong Kong, it has been necessary to construct clinics and other health facilities to provide the essential medical care.

The expanding educational and cultural exchange program of the Department of State provides some funds for training in medical and health activities. Involved in the program are Americans who study or teach abroad as well as nationals of other countries who come to the United States for health-related teaching or studies. This activitity is small but important, accounting for about 3 percent of annual outlays of the educational exchange programs.

AID, in its principal mission of assisting economic and social progress of underdeveloped countries, has a number of programs designed to improve the health-related resources of these countries. These activities range from assistance in the development and construction of medical schools and the training of health workers to the establishment of potable water supplies. Among the health programs of AID, strong emphasis also has been placed on the control of communicable diseases.

The Peace Corps now has 11,000 corpsmen assigned to 46 countries. Some of them are providing direct medical and paramedical care in the countries to which they are assigned while others are providing technical assistance concerning advanced methods of preventive medicine, sanitation, and nutrition. In addition, funds are provided for medical treatment of corpsmen.

Within the President's international health program, AID and the Peace Corps plan to increase their activities in the lesser developed countries during fiscal 1967 in pursuit of these objectives: to help meet the health manpower needs of developing nations; to combat malnutrition; to control and eradicate diseases; and to cooperate in worldwide efforts to deal with population problems. This program was described in more detail in the President's International Education and Health Message to Congress dated February 2, 1966.

State, AID, and the Peace Corps have established an extensive number of working relationships with HEW to coordinate activities of mutual interest. There are at least eight interagency committees on which one of these agencies has membership together with HEW. There are in existence a number of agreements for the utilization, usually on a reimbursable basis, of HEW scientific and technical personnel by State, AID, and the Peace Corps. An example of recent activity exists in the Volta measles study conducted in Africa. On this successful project, although there was no formal agreement between the agencies, NIH furnished the technical personnel and the vaccine and AID furnished the necessary vehicles, jet injectors, and additional supplies required. Furthermore, it has been agreed that State will provide foreign policy guidance, advice, and clearance on all foreign research grants and activities.

Funds for medical and health-related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	1.0	1.1	1.1
Federal grants and payments for hospital and health care in non-Federal facilities	.3	.3	.3
Medical research: Conduct of research	.9	2.1	2.2
Training, including training for research	5.2	5.7	8.0
Preventive and community services	61.2	68.3	96.0
Construction of hospitals and health facilities	7.4	11.6	15.7
Total	76.0	89.1	123.3

Veterans Administration

The Veterans Administration is charged with the responsibility of providing hospital, nursing home, domiciliary, and medical services to all eligible veterans of the United States Armed Forces. This responsibility is administered by the Department of Medicine and Surgey, one of the three principal operating units of the VA.

All of the 25 million living veterans are potentially eligible for hospital or medical services under VA auspices. The primary Federal responsibility under the veterans hospital and medical care program is to the service disabled who number an estimated 3½ million veterans. Other veterans may receive inpatient care and treatment in VA facilities for nonservice-connected ailments only if beds are available and if the veteran is unable to defray expenses of necessary hospital or domiciliary care. Medical services may be furnished on an outpatient basis for service-connected disabilities; for nonservice-connected disabilites they may be furnished only to veterans who have been determined to need hospital care and whose admission to a hospital has been scheduled or who require post-hospital treatment to complete hospital care.

In fiscal year 1966, the VA rendered treatment to eligible beneficiaries at 167 hospitals, 18 domiciliary homes and restoration centers, 67 outpatient clinics and 12 subclinic offices. In those cases where VA facilities are not available, services are provided through contractual arrangements in other hospitals. This complex of facilities represents the largest hospital system, in terms of number of beds, in the country. It is estimated that in 1967 the system will directly operate an average of 117,034 hospital beds, 3,000 nursing home beds, and 14,334 domiciliary home and restoration center beds. In these facilities average daily patient loads of 108,357 hospital patients, 2,790 nursing home patients, and 13,500 domiciliary members will be cared for. In addition, the Veterans Administration will contract for the care of an average of 2,087 veterans in community nursing homes, 1,316 patients in other Federal hospitals, and 1,262 patients in non-Federal hospitals. In addition, the Veterans Administration makes grants to State soldiers' homes as partial support for an average of 7,950 veterans provided domiciliary care, and 1,400 provided nursing home care. About 70 percent of the beds in VA hospitals are occupied by nonservice-connected cases. Forty-four percent of the psychiatric patients have service-connected disabilities, whereas approximately 10 percent of the nonpsychiatric patients are being treated for service-connected disabilities. Approximately 6.3 million visits are anticipated to be made to VA clinics and contract physicians and dentists for both medical and dental care.

The Veterans Administration Cancer Chemotherapy Study was organized in May 1956. Thirteen hospitals are now participating in the study. The VA study is concentrating in the areas of cancer of the lung, esophagus, stomach, large bowel, bladder, and prostate, leukemia and multiple myeloma.

These cancer chemotherapy study groups have developed the ability to undertake large-scale studies and evaluations of various chemotherapy drugs and regimens as well as more conventional modalities for control and cure of this disease. Cancer victims occupy approximately 10 percent of VA hospital beds at all times. This population is a fruitful source of clinical material for studies on cancer while VA patients gain the benefit of the most modern therapy. Treatment techniques are closely scrutinized, fully evaluated, and constantly improved as a result of VA studies and VA physicians.

In fiscal year 1965, the VA cancer chemotherapy study cost $995,000 in National Cancer Institute funds and $200,000 in VA research funds. The VA physicians time and patient care costs are in addition to these amounts. It is anticipated that costs will continue in the same order of magnitude for fiscal year 1966.

A number of factors have a bearing on the demand for hospital, nursing home, and domiciliary care. With the passage of P.L. 89–358, the veteran population is not expected to decline as rapidly as previously projected; however, the total veteran population is declining and the age of the veteran will increase. The improvements in medical practice have significant bearings in the changes in VA patient load and the availability of financing of care for the aged veteran under the Social Security program should have a significant, though, at this point, undetermined effect on the VA patient loads.

The VA in addition to its primary medical mission of patient care conducts a research program which is financed both from the direct appropriation to the agency and through grants from private and governmental agencies.

In carrying out these activities, the VA and HEW cooperate through (1) contracts between the two agencies for care of each agency's beneficiaries in the other agency's facilities, (2) VA supply services on certain items for Public Health Service hospitals, (3) reimbursement for VA activities in carrying on NIH chemotherapy program and PHS medical stockpile programs, (4) VA membership on certain NIH study sections and NIH participation on VA research review committees, (5) VA membership on the advisory council for regional medical centers (the heart, stroke, cancer program) and council on aging, (6) VA use Social

Security numbering system, and (7) joint sponsorship of research study of susceptibility to health frauds and misrepresentation.

Funds for medical and health related activities

[In millions of dollars]

Category	Expenditures		
	1965 actual	1966 estimate	1967 estimate
Hospital and medical care in Federal facilities	1,102.2	1,160.4	1,209.7
Federal grants and payments for hospital and health care in non-Federal facilities	16.0	22.8	25.8
Medical research:			
Conduct of research	37.1	42.6	43.0
Research facilities	3.8	7.8	6.4
Training, including training for research	28.1	33.6	34.1
Construction of hospitals and health facilities	78.6	75.9	67.5
Total	1,256.7	1,343.0	1,386.5

Enclosure C

Major Interagency Committees Related to Health Activities

The following report on major interagency committees related to health activities reflects a part of the effort being made by individual Federal agencies to coordinate their activities in the areas of health research, health care and health education. The report does not include public advisory committees on which there are no agency representatives. Although this report indicates only Federal representation on each committee, many such committees also include knowledgeable individuals from universities, private industry and State and local governments in their membership.

The function of the interagency committees which are specifically described in this report is to act in an advisory and coordinating capacity on health related programs and problems. In addition to providing for the coordination of, and advice on, health activities, these interagency committees help to insure the maximum utilization of relatively scarce health personnel and health facilities.

The interagency committees described in this report are grouped under the agency which chairs the committee, or which has the primary interest in the activities of the committee. There are a number of interagency committees which are not covered by this report which are either limited in scope, or related to a regional or local situation. A number of the interagency committees included in this report have subcommittee organizations which are not included in this report in all cases.

I. DEPARTMENT OF COMMERCE

1. *National Facilitation Committee:*

Function: To simplify, standardize and reduce, consistent with national security, national revenue and the public health and safety, formalities that unduly burden the movement of persons and goods across national frontiers.

Representation: Departments of State, Commerce, Health, Education, and Welfare, Agriculture, Defense, Justice and Treasury; Federal Aviation Agency; Interstate Commerce Commission; Civil Aeronautics Board.

2. *Interdepartmental Committee on Radiation Preservation of Food:*

Function: To provide motivation and broad guidance for the program, to achieve the highest level of participation by Government agencies and industry and to effect a transition of program responsibility from the military departments to other Government agencies and to industry as quickly as practical.

Representation: Departments of State, Commerce, Interior, Agriculture, Health, Education, and Welfare and Defense; Atomic Energy Commission; Agency for International Development.

II. DEPARTMENT OF DEFENSE

1. *Water Development Committee for Appalachia:*

Function: To coordinate the studies on water resources of the Corps of Engineers, other Federal agencies and the States concerned, in connection with the Appalachian Regional Development Act of 1965.

Representation: Departments of Agriculture, Commerce, Defense, Interior and Health, Education, and Welfare; Federal Power Commission; Tennessee Valley Authority.

2. *Armed Forces Epidemiological Board:*

Function: To provide military departments with scientific and research assistance and advice on matters pertaining to problems in preventive medicine.

Representation: Departments of Health, Education, and Welfare and Defense.

Commissions: The following Commissions of the Armed Forces Epidemiological Board are in current operation:

Commission on Cutaneous Diseases:

Function: To maintain surveillance, and provide advice, research and other forms of direct help on cutaneous diseases, particularly in the area of venereal disease.

Commission on Environmental Hygiene:

Function: To advise on matters pertaining to problems in preventive medicine related to environmental hygiene.

Commission on Influenza:

Function: To advise on matters pertaining to the prevention and control of influenza.

Commission on Military Accidents:

Function: To provide scientific and research assistance and advice on matters pertaining to problems related to the prevention of military accidents.

Commission on Viral Infection:

Function: To provide scientific and research assistance and advice on matters pertaining to problems related to the prevention and cure of viral infection.

3. *Army Medical Service Advisory Committee on Preventive Dentistry:*

Function: To study and make recommendations to the Surgeon General of the Army on programs directed toward the prevention of oral diseases and injuries.

Representation: Departments of Defense and Health, Education, and Welfare.

4. *Committee on Hearing and Bio-Acoustics:*

Function: To consider problems of a scientific and technical nature concerning the direct effect of accoustic energy on man.

Representation: Departments of Defense and Health, Education, and Welfare; Federal Aviation Agency.

5. *Federal Medical Education for National Defense Council:*

Function: To establish policies for the Medical Education for National Defense Program.

Representation: Departments of Defense and Health, Education, and Welfare; Office of Emergency Planning.

6. *Interdepartmental Committee on National Blood Program Research:*

Function: To obtain necessary collaboration among agencies concerned with research in support of the National Blood Program, and to assure a coordinated research and development program funded and administered by the participating agencies.

Representation: Departments of Defense, and Health, Education, and Welfare; Atomic Energy Commission; Veterans' Administration.

7. *Intra-governmental Procurement Advisory Council on Drugs:*

Function: To improve specifications for drug procurement, improve quality control and exchange of procurement information.

Representation: Departments of Defense, and Health, Education, and Welfare; Veterans' Administration; General Services Administration.

8. *Task Force, Essential Survival Items, Health Supplies and Equipment:*

Function: To determine the health supply and equipment items essential to survival following a nuclear attack.

Representation: Departments of Defense and Health, Education, and Welfare; Office of Emergency Planning; Veterans' Administration.

9. *Task Force, Essential Survival Items, Sanitation and Water:*
Function: To determine the sanitation and water supply items essential to survival following a nuclear attack.
Representation: Departments of Defense, Health, Education, and Welfare, and Housing and Urban Development; Office of Emergency Planning.
10. *Uniformed Services Liaison Committee:*
Function: To advise and assist the Executive Director, Office of Dependent's Medical Care, on all matters pertaining to the implementation and operation of the cililian part of the Dependents' Medical Care Program.
Representation: Departments of Defense and Health, Education, and Welfare.

III. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

1. *Executive Committee, President's Council on Aging:*
Function: To coordinate the proposed projects and recommendations of the several subcommittees of the President's Council on Aging, with respect to the Federal Government's responsibilities to problems of aging.
Representation: Departments of Health, Education, and Welfare, Treasury, Agriculture, Commerce, Labor, Housing and Urban Development; Bureau of the Budget; Civil Service Commission; Veterans' Administration.
2. *Subcommittee on Welfare Services* (A subcommittee of the President's Council on Aging):
Function: To study the relationship and problems related to welfare services for older people.
Representation: Departments of Health, Education, and Welfare and Agriculture; Veterans' Administration.
3. *Subcommittee on Nursing Homes* (A subcommittee of the President's Council on Aging):
Function: To develop guidelines for studies on nursing home problems by several Federal agencies concerned with this area of service to the aging.
Representation: Departments of Health, Education, and Welfare, Commerce, Agriculture, and Housing and Urban Development; Veterans Administration.
4. *Subcommittee on Senior Centers* (A subcommittee of the President's Council on Aging):
Function: To study the potential function of senior centers, alternative patterns of organization and sponsorship; the incidence and distribution of centers; the current programs and activities and the roles which the Federal Government could play in the development of such centers.
Representation: Departments of Health, Education, and Welfare, Agriculture; Veterans Administration.
5. *President's Committee on Employment of the Handicapped, Medical Committee:*
Function: To conduct information programs to impress employers and physicians with the concept of the whole worker, his physical environment and the ability to perform occupational tasks in business and industry despite physical irregularities.
Representation: Departments of Health, Education, and Welfare and Defense; Civil Service Commission; Veterans Administration.
6. *The Mental Retardation State Planning Grant Review Committee:*
Function: To review applications for State Mental Retardation Planning Grants.
Representation: Departments of Health, Education, and Welfare, Labor, and Interior.
7. *Joint Committee on Rural Sanitation:*
Function: To assist in establishing uniform standards for rural and suburban sanitation and advise member agencies on the substance and application of such standards.
Representation: Departments of Health, Education, and Welfare, Interior, Agriculture, Defense, and Housing and Urban Development; Veterans Administration; Tennessee Valley Authority.
8. *Joint Task Force Committee on HEW Services and Housing:*
Function: To coordinate the programs of the agencies in the area of needs of families of low income.
Representation: Departments of Health, Education, and Welfare and Housing and Urban Development.

9. *Interdepartmental Committee for Children and Youth:*

Function: To aid in the developing of appropriate working relationships among Federal agencies concerned, and between the Federal Government and State commissions or committees for children and youth.

Representation: Departments of Health, Education, and Welfare, State, Defense, Agriculture, Interior, Justice, Labor, and Housing and Urban Development; Veterans Administration; Bureau of the Budget; U.S. Information Agency; Library of Congress; President's Council on Physical Fitness; President's Committee on Juvenile Delinquency.

10. *Internal Advisory Health Committee of the Agency for International Development:*

Function: To coordinate health activities.

Representation: Department of Health, Education, and Welfare; Agency for International Development; Peace Corps.

11. *Inter-Medical Television Network Committee:*

Function: To develop policies and operating plan for the television network public health hospitals and military hospitals in the Washington area.

Representation: Departments of Health, Education, and Welfare and Defense.

12. *Interdepartmental Committee on Sewage and Waste Disposal from Vessels:*

Function: To determine the most effective and economical means of sewage and garbage disposal from ships in the Great Lakes, and inland and coastal waters within the jurisdiction of the United States to minimize contamination of waters used for potable, recreational, and other purposes.

Representation: Departments of Health, Education, and Welfare, Defense, Commerce, Treasury, and Agriculture.

13. *Interagency Task Group on Emergency Water Resources Management:*

Function: To advise on the development of programs which can be applied to the management of water supplies in a civil defense emergency.

Representation: Departments of Health, Education, and Welfare, Commerce, Agriculture, Interior, and Defense; Tennessee Valley Authority; Office of Emergency Planning.

14. *Interagency Committee on Training and Education of Federal Hospital Administrative Personnel:*

Function: To develop and coordinate training and education plans and programs for Federal hospital administrative personnel.

Representation: Departments of Health, Education, and Welfare and Defense; Veterans' Administration.

15. *Interagency Committee on Medical Records:*

Function: To study and make recommendations on a common system of medical records and disease nomenclature.

Representation: Departments of Health, Education, and Welfare, and Defense; Veterans' Administration.

16. *Gorgas Memorial Institute of Tropical and Preventive Medicine, Board of Directors:*

Function: To provide for the maintenance and operation of a research laboratory to be known as the Gorgas Memorial Laboratory.

Representation: Departments of Health, Education, and Welfare, Defense and State.

17. *Working Group of the Federal Radiation Council:*

Function: To advise concerned agencies with respect to radiation matters directly or indirectly affecting health.

Representation: Departments of Health, Education, and Welfare, Labor, Defense, and Commerce; Atomic Energy Commission.

18. *National Research Council, Committee on Toxicology:*

Function: To integrate available toxicologic knowledge.

Representation: Departments of Health, Education, and Welfare and Defense; National Aeronautics and Space Administration; Atomic Energy Commission.

19. *Federal Committee on Pest Control:*

Function: To review the programs of Federal agencies for control of animal and plant life which adversely affect man's interests. Advise Federal agencies concerning such programs to achieve the desired results with minimum undesirable effects.

Representation: Departments of Health, Education, and Welfare, Interior, Agriculture, and Defense.

20. *National Advisory Councils to the National Institutes of Health:* The National Advisory Councils were established by statute to advise the Surgeon General on programs and activities within the purview of the National Institutes of Health. These groups have functioned as public advisory groups. Their status as interdepartmental committees has developed as a result of the statutory "ex officio" designation for representatives from certain Federal agencies, primarily the Department of Defense and the Veterans' Administration. The basic committee membership is made up of knowledgeable private citizens from outside of the Federal Government. The National Advisory Councils are:

National Advisory Health Council.
National Advisory Allergy and Infectious Diseases Council.
National Advisory Arthritis and Metabolic Diseases Council.
National Advisory Cancer Council.
National Advisory Child Health and Human Development Council.
National Advisory Dental Research Council.
National Advisory General Medical Sciences Council.
National Advisory Heart Council.
National Advisory Mental Health Council.
National Mental Health Manpower Studies Committee.
National Advisory Neurological Diseases and Blindness Council.
National Advisory Council on Health Research Facilities.
National Advisory Research Resources Committee.
National Advisory Community Health Committee.
Board of Regents, National Library of Medicine.

Reference: *Public Advisory Groups: Authority, Structure, Functions,* U.S. Department of Health, Education, and Welfare, Public Health Service, June 1, 1963.

IV. DEPARTMENT OF THE INTERIOR

1. *Water Resources Council:*
 Function: To maintain a continuing study, and make recommendations regarding, the adequacy of supplies of water necessary to meet the water requirements in each water resources region in the United States.
 Representation: Departments of Interior, Health, Education, and Welfare, Agriculture, and Defense; Federal Power Commission.
2. *Advisory Committee to the Silicosis Study of Metal Miners:*
 Function: To direct the administrative aspects of the joint Public Health Service and Bureau of Mines silicosis study.
 Representation: Departments of Health, Education, and Welfare and Interior.
3. *Federal Advisory Committee on Water Pollution Control Data:*
 Function: To coordinate Federal activities in acquiring water pollution data from streams, lakes, reservoirs, estuaries, and ground waters.
 Representation: Departments of Interior, Agriculture, Defense, Commerce, Housing and Urban Development, and Health, Education, and Welfare; Atomic Energy Commission; Federal Power Commission; Tennessee Valley Authority; Bureau of the Budget.

V. DEPARTMENT OF LABOR

1. *Advisory Safety Committee on Farm Employed Youth:*
 Function: To reduce the number of deaths and injuries occurring to minors under 18 years of age who are employed as paid workers on farms.
 Representation: Departments of Health, Education, and Welfare, Labor, and Agriculture.
2. *Advisory Committee on Institutional Safety Programs:*
 Function: To advise on safety programs for institutions for juveniles and mental retardees.
 Representation: Departments of Labor, Health, Education, and Welfare and Justice.

VI. POST OFFICE DEPARTMENT

1. *Post Office Advisory Committee:*
 Function: To advise the Post Office Department concerning the mailing of poisonous materials.
 Representation: Departments of Health, Education, and Welfare and Post Office.

VII. ATOMIC ENERGY COMMISSION

1. *Interagency Committee on Radiological Assistance:*
Function: To maintain a continuous liaison between the various Federal agencies with respect to emergency radiological assistance. To disseminate information with regard to plans and actions taken by the various agencies under the Interagency Radiological Plan.
Representation: Departments of Defense, Health, Education, and Welfare, Commerce, Labor, Treasury, and Post Office; Atomic Energy Commission; the General Services Administration; the Interstate Commerce Commission; National Aeronautics and Space Administration.

VIII. NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

1. *Science Information Exchange Advisory Board:*
Function: To provide a mechanism for exchange by participating agencies of administrative data of grants and contracts awarded by the Federal Government agencies, major foundations and voluntary agencies.
Representation: Departments of Defense, Health, Education, and Welfare, Agriculture, Interior, State, and Commerce; Federal Aviation Agency; National Science Foundation; Atomic Energy Commission; National Aeronautics and Space Administration.
2. *NASA Research Advisory Committee on Biotechnology and Human Research:*
Function: To provide advice on work on research and technology in progress by NASA and other agencies as appropriate and to make recommendations on research and technology problems which may warrant future investigation by or for NASA.
Representation: Departments of Health, Education, and Welfare and Defense; National Aeronautics Space Administration; the Federal Aviation Agency.

IX. NATIONAL SCIENCE FOUNDATION

1. *Advisory Council for Manpower and Education Studies Programs:*
Function: To guide the development of Federal programs of statistics on scientific personnel.
Representation: Departments of Health, Education, and Welfare, Commerce, Labor and Agriculture; Office of Emergency Planning; Atomic Energy Commission; National Aeronautics and Space Administration; Civil Service Commission; Selective Service System; National Science Foundation.
2. *Behavioral Sciences Panel of the Federal Council for Science and Technology:*
Function: To determine what the various Federal agencies are doing in the field of behavioral science and to assist in the coordination of such programs.
Representation: Departments of Health, Education, and Welfare, Commerce, Interior, Defense, State and Agriculture; National Aeronautics and Space Administration; National Science Foundation.
3. *Federal Interagency Chemistry Representatives:*
Function: To coordinate Federal support of basic research in chemistry.
Representation: Departments of Health, Education, and Welfare and Defense; Atomic Energy Commission; National Science Foundation.

X. VETERANS' ADMINISTRATION

1. *Federal Advisory Council on Medical Training Aids:*
Function: To exchange information on production of medical training aids and to avoid duplication in this area.
Representation: Departments of Health, Education, and Welfare and Defense; Veterans' Administration.
2. *Review Committee, Veterans' Administration Hospital Computer Project:*
Function: To provide advice and counsel to the Veterans' Administration through review plans and progress in application of ADP techniques to operation of medical care units.
Representation: Department of Health, Education, and Welfare; Veterans' Administration; National Bureau of Standards.

3. *Advisory Committee to the Psychiatry and Neurology and Psychology Service of the Veterans' Administration, Research Subcommittee:*

Function: To advise on questions related to professional services for the Advisory Committee to the psychiatry and neurology and psychology service of the Veterans' Administration.

Representation: Department of Health, Education, and Welfare; Veterans' Administration.

XI. OTHER INTERAGENCY HEALTH RELATED COMMITTEES

1. *Federal Council for Science and Technology:*

Function: To consider problems and developments in the fields of science and technology affecting more than one Federal agency and to recommend policies to provide more effective planning and administration of Federal scientific and technological programs.

Representation: Departments of Defense, Agriculture, Commerce, Health, Education, and Welfare and Interior; Atomic Energy Commission; National Science Foundation; National Aeronautics and Space Administration; the Executive Office of the President. Official Observers include Federal Aviation Agency; Department of State.

2. *Interagency Committee on Nutrition Education:*

Function: To make recommendations with regard to basic nutrition concepts, and to disseminate materials on nutrition education.

Representation: Departments of Health, Education, and Welfare, Interior, and Agriculture; American Red Cross.

Appendix B

Reorganization Plan No. 3 of 1966

The White House, *April 25, 1966.*

To the Congress of the United States:

I transmit herewith Reorganization Plan No. 3 of 1966, prepared in accordance with the Reorganization Act of 1949, as amended, and providing for reorganization of health functions of the Department of Health, Education, and Welfare.

I

Today we face new challenges and unparalleled opportunities in the field of health. Building on the progress of the past several years, we have truly begun to match the achievements of our medicine to the needs of our people.

The task ahead is immense. As a nation, we will unceasingly pursue our research and learning, our training and building, our testing and treatment. But now our concern must also turn to the organization of our Federal health programs.

As citizens we are entitled to the very best health services our resources can provide.

As taxpayers, we demand the most efficient and economic health organizations that can be devised.

I ask the Congress to approve a reorganization plan to bring new strength to the administration of federal health programs.

I propose a series of changes in the organization of the Public Health Service that will bring to all Americans a structure modern in design, more efficient in operation and better prepared to meet the great and growing needs of the future. Through such improvements we can achieve the full promise of the landmark health legislation enacted by the 89th Congress.

I do not propose these changes lightly. They follow a period of careful deliberation. For many months the Secretary of Health, Education, and Welfare and the Surgeon General have consulted leading experts in the nation—physicians, administrators, scientists, and public health specialists. They have confirmed my belief that modernization and reorganization of the Public Health Service are urgently required and long overdue.

II

The Public Health Service is an operating agency of the Department of Health, Education, and Welfare. It is the principal arm of the Federal Government in the field of health. Its programs are among those most vital to our well-being.

Since 1953 more than 50 new programs have been placed in the Public Health Service. Its budget over the past 12 years has increased tenfold—from $250 million to $2.4 billion.

Today the organization of the Public Health Service is clearly obsolete. The requirement that new and expanding programs be administered through an organizational structure established by law more than two decades ago stands as a major obstacle to the fulfillment of our nation's health goals.

As presently constituted, the Public Health Service is composed of four major components:

National Institutes of Health;
Bureau of State Services;
Bureau of Medical Services;
Office of the Surgeon General.

Under present law, Public Health Service functions must be assigned only to these four components.

This structure was designed to provide separate administrative arrangements for health research, programs of state and local aid, health services, and executive staff resources. At a time when these functions could be neatly compartmentalized, the structure was adequate. But today the situation is different.

Under recent legislation many new programs provide for an integrated attack on specific disease problems or health hazards in the environment by combining health services, state and local aid, and research. Each new program of this type necessarily is assigned to one of the three operating components of the Public Health Service. Yet none of these components is intended to administer programs involving such a variety of approaches.

Our health problems are difficult enough without having them complicated by outmoded organizational arrangements.

But if we merely take the step of integrating the four agencies within the Public Health Service we will not go far enough. More is required.

III

The Department of Health Education, and Welfare performs major health or health-related functions which are not carried out through the Public Health Service, although they are closely related to its functions. Among these are—

health i surance for the aged, administered through the Social Security Administration;

medical assistance for the needy, administered through the Welfare Administration;

regulation of the manufacture, labelling, and distribution of drugs, carried out through the Food and Drug Administration; and

grants-in-aid to States for vocational rehabilitation of the handicapped, administered by the Vocational Rehabilitation Administration.

Expenditures for health and health-related programs of the Department administered outside the Public Health Service have increased from $44 million in 1953 to an estimated $5.4 billion in 1967.

As the head of the Department, the Secretary of Health, Education, and Welfare is responsible for the administration and coordination of all the Department's health functions. He has clear authority over the programs I have just mentioned.

But today he lacks this essential authority over the Public Health Service. The functions of that agency are vested in the Surgeon General and not in the Secretary.

This diffusion of responsibility is unsound and unwise.

To secure the highest possible level of health services for the American people the Secretary of Health, Education, and Welfare must be given the authority to establish—and modify as necessary—the organizational structure for Public Health Service programs.

He must also have the authority to coordinate health functions throughout the Department. The reorganization plan I propose will accomplish these purposes. It will provide the Secretary with the flexibility to create new and responsive organizational arrangements to keep pace with the changing and dynamic nature of our health programs.

My views in this respect follow a basic principle of good Government set by the Hoover Commission in 1949 when it recommended: "that the department head should be given authority to determine the organization within his department."

IV

In summary, the Reorganization Plan would—

transfer to the Secretary of Health, Education, and Welfare the functions now vested in the Surgeon General of the Public Health Service and in its various subordinate units (this transfer will not affect certain statutory advisory bodies such as the National Advisory Cancer and Heart Councils);

abolish the four principal statutory components of the Public Health Service, including the offices held by their heads (the Bureau of Medical Services, the Bureau of State Services, the National Institutes of Health exclusive of its several research institutes, such as The National Cancer and Heart Institutes and the Office of the Surgeon General);

authorize the Secretary to assign the functions transferred to him by the plan to officials and entities of the Public Health Service and to other agencies of the Department as he deems appropriate;

Thus, the Secretary would be—

enabled to assure that all health functions of the Department are carried out as effectively and economically as possible;

given authority commensurate with his responsibility; and

made responsible in fact for matters for which he is now, in any case, held accountable by the President, the Congress, and the people.

V

I have found, after investigation, that each reorganization included in the accompanying reorganization plan is necessary to accomplish one or more of the purposes set forth in section 2(a) of the Reorganization Act of 1949, as amended.

Should the reorganizations in the accompanying reorganization plan take effect, they will make possible more effective and efficient administration of the affected health programs. It is, however, not practicable at this time to itemize the reductions in expenditures which may result.

I strongly recommend that the Congress allow the reorganization plan to become effective.

LYNDON B. JOHNSON.

REORGANIZATION PLAN NO. 3 OF 1966

(Prepared by the President and transmitted to the Senate and the House of Representatives in Congress assembled, April 25, 1966, pursuant to the provisions of the Reorganization Act of 1949, 63 Stat. 203, as amended.)

PUBLIC HEALTH SERVICE

SECTION 1. *Transfer of functions.* (a) Except as otherwise provided in subsection (b) of this section, there are hereby transferred to the Secretary of Health, Education, and Welfare (hereinafter referred to as the Secretary) all functions of the Public Health Service, of the Surgeon General of the Public Health Service, and of all other officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service.

(b) This section shall not apply to the functions vested by law in any advisory council, board, or committee of or in the Public Health Service which is established by law or is required by law to be established.

SEC. 2. *Performance of transferred functions.* The Secretary may from time to time make such provisions as he shall deem appropriate authorizing the performance of any of the functions transferred to him by the provisions of this reorganization plan by any officer, employee, or agency of the Public Health Service or of the Department of Health, Education, and Welfare.

SEC. 3. *Abolitions.* (a) the following agencies of the Public Health Service are hereby abolished:

(1) The Bureau of Medical Services, including the office of Chief of the Bureau of Medical Services.

(2) The Bureau of State Services, including the office of Chief of the Bureau of State Services.

(3) The agency designated as the National Institutes of Health (42 U.S.C. 203), including the office of Director of the National Institutes of Health (42 U.S.C. 206(b)) but excluding the several research Institutes in the agency designated as the National Institutes of Health.

(4) The agency designated as the Office of the Surgeon General (42 U.S.C. 203(1)), together with the office held by the Deputy Surgeon General (42 U.S.C. 206(a)).

(b) The Secretary shall make such provisions as he shall deem necessary respecting the winding up of any outstanding affairs of the agencies abolished by the provisions of this section.

SEC. 4. *Incidental transfers.* As he may deem necessary in order to carry out the provisions of this reorganization plan, the Secretary may from time to time effect transfers within the Department of Health, Education, and Welfare of any of the records, property, personnel, and unexpended balances (available or to be made available) of appropriations, allocations, and other funds of the Department which relate to functions affected by this reorganization plan.

[For immediate release, Monday, April 25, 1966]

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
Washington, D.C.

Secretary of Health, Education, and Welfare John W. Gardner, following President Johnson's Message to the Congress calling for reorganization of the Public Health Service, today issued further details on the proposed plan as it applies to the internal organization of the Service.

Secretary Gardner stressed the need for future Secretaries of Health, Education, and Welfare to have the power to reorganize the Service and its components as changing times may require.

"It is important, as the President points out in his message, that the Service be brought up to date. For the long run, any Secretary of Health, Education, and Welfare should be able to provide the Surgeon General and his staff with the sort of organization which will best serve the health needs of the Nation. It is axiomatic that in a society such as ours, our institutions be continuously ready to make these necessary adaptations."

Secretary Gardner said that the plan envisions the establishment of five operating Bureaus plus the Office of the Surgeon General.

Under the five-Bureau plan, if the powers are granted to the Secretary, the following regroupings would take place:

The Office of the Surgeon General would include all the activities it now conducts, with the exception of the Division of Health Mobilization which would be located in the Bureau of Health Services. In addition, the Office of the Surgeon General would assume additional central responsibilities for management of grant and contract activities, processing statistical data for Service-wide use, programs in planning and analysis. International health, scientific and public communications, interagency liaison and personnel would be strengthened. The National Library of Medicine and the National Center for Health Statistics remain as an integral part of the Office of the Surgeon General with the chiefs of these units reporting to him.

The Bureau of Health Services would be made up of the present Divisions of Medical Care Administration, Hospital and Medical Facilities (Hill-Burton), Indian Health, Hospitals, and Health Mobilization, plus the Bureau of Prisons, Peace Corps and the Coast Guard medical programs and portions of the Divisions of Community Health Services and Chronic Diseases.

The Bureau of Health Manpower would include the present Divisions of Dental Health and Nursing, plus those activities of the Divisions of Hospital and Medical Facilities and Community Health Services which relate to the development of health manpower.

The Bureau of Disease and Injury Prevention and Control would be made up of the Communicable Disease Center, the Arctic Health Research Center, the Offices of Pesticides and Solid Waste Disposal, and the Divisions of Accident Prevention, Environmental Engineering and Food Protection, Air Pollution, Occupational Health, Radiological Health, and Foreign Quarantine, plus the Disease control programs of the Division of Chronic Diseases.

The National Institute of Mental Health would incorporate the present activities of the existing Institute plus the Public Health Service Hospitals for drug addiction at Lexington, Kentucky and Fort Worth, Texas; and would serve as the principal focus for research and control programs related to alcoholism.

The National Institutes of Health would remain a bureau of the Service in parallel with the other bureaus described above. To the present structure of the Institutes would be added a National Institute of Environmental Health Sciences.

Under the present organization the Public Health Service consists of four Bureaus—Bureau of Medical Services, Bureau of State Services, National Institutes of Health and the Office of the Surgeon General which encompasses the National Center for Health Statistics, the National Library of Medicine, the Divisions of Health Mobilization, Public Health Methods, Finance, Administrative Services and Internal Audit, the Offices of Personnel, International Health, Information and Publications, and Equal Health Opportunity.

April 18, 1966.

Memorandum to: Secretary.
From: Surgeon General William H. Stewart.
Subject: Reorganization of the Public Health Service.

On January 18 I submitted to you a preliminary statement of the goals toward which the American health partnership should be moving, the role of the Public Health Service in achieving these goals, and the pattern of organization which can best equip us to discharge our responsibilities.

Since that time I have had the benefit of the final report of the Corson Committee and further discussions with thoughtful and competent people both within and outside the Service. I feel that the time is now ripe for a definitive statement of our aims and the organizational structure which will, in my judgment, serve them best. This memorandum is designed to constitute such a statement.

My fundamental thesis is that the health of the American people, in its totality shall be the overriding concern of the Public Health Service and the measure of our success or failure. Our ultimate commitment is not to agencies or institutions but to people. In this context the Surgeon General should be the individual to whom the public may turn when their expectations for health care are not being fulfilled.

The composition of the eight major components of the reorganized Public Health Service has been agreed upon in substance by the Bureau Chiefs and other top staff. The following descriptions and the appended chart, showing program elements may therefore be considered as firm and final recommendations.

The plan is ready for immediate implementation. Certain aspects of it will involve highly complex inter-relationships. Although certain steps are proposed for immediate action, full development will require additional steps over a longer period of time. Two of these complex areas, described in the appropriate sections of the following text, are (1) the relationships between the proposed National Institute of Environmental Health Sciences and the categorical programs responsible for control of environmental hazards to health; and (2) the development of a system of grants management that will enable each echelon and component of the Service to derive full benefit from and make its maximum contribution to the extramural effort.

A. BUREAU OF HEALTH SERVICES

The new Bureau of Health Services is designed as a central resource for improving the quality and accessibility of health care for the American people. It will have the primary responsibility to develop and maintain effective working relationships with private medicine, public and private institutions and organizations and official agencies in the health care field, and to stimulate and support innovations in the delivery of health care.

The Service would welcome this assumption of central responsibility for health on behalf of the people. I believe it is capable of exercising a form of leadership in health that is now impossible because responsibilities are diffused among many agencies at the Federal level—a diffusion which is reflected throughout state and community programs. There is, in medicine and its allied sciences, a leading edge of research and development which is piercing the frontiers of existing knowledge. This advance requires support and guidance in directing its efforts toward those needs which are greatest. Also required is a strong movement that will convert science into practice and channel new developments into the mainstream of medicine. Both of these are logical functions of the Public Health Service stemming from the stature of leadership to which we aspire.

Clearly, such responsibility cannot be pre-empted. It must be earned. It can only be earned by an agency that is oriented toward the future and organized so as to make the most effective use of its resources.

In the organization plan which follows, each major component will be characterized by commonality of purpose, achieved through the harnessing of complementary skills. I believe that such an organization can attract and retain the number and quality of personnel it needs to fulfill its mission, and that it can furnish the full measure of leadership, stimulation, and guidance required from the Federal government in advancing the Nation's health.

Organization of the Public Health Service

The organization plan which I consider essential for these purposes would consist of eight major components, as follows:

A. Five operating Bureaus: Bureau of Health Services, Bureau of Health Manpower, Bureau of Disease and Injury Prevention and Control, National Institutes of Health, and a National Institute of Mental Health;

B. Two major activities reporting directly to the Surgeon General: The National Library of Medicine and National Center for Health Statistics;

C. The Office of the Surgeon General.

The new Bureau will contain all PHS activities which take part in establishing quality standards for health services. It will contain all our programs which provide medical care to legal beneficiaries—the general hospitals and clinics, the Indian program and the health care provided to Federal employees, the Coast Guard and prisons. The Bureau will also discharge the PHS responsibilities in meeting health needs in national emergencies.

By combining our direct medical care activities with programs which support the planning and construction of health facilities and the development of new and improved personal health services, the Bureau of Health Services will enable the

Public Health Service to undertake, for the first time, a fully coordinated effort to improve the quality and accessibility of health care for the nation as a whole.

The Bureau of Health Services will be made up of the present Divisions of Medical Care Administration, Hospital and Medical Facilities, Indian Health, Hospitals, and Health Mobilization, plus our Bureau of Prisons and Peace Corps medical programs and portions of the Divisions of Community Health Services and Chronic Diseases.

B. BUREAU OF HEALTH MANPOWER

The Bureau of Health Manpower will concentrate the rapidly growing Federal support of programs designed to provide additional and better qualified manpower for health. The Bureau will serve as a central point of contact for educators and others involved in planning and carrying out education and training programs for health professional and subprofessional personnel. It will also constitute a national source of reliable information and projection as to manpower needs and programs designed to meet them.

The Bureau will carry out our present and anticipated programs in the manpower field, except for research training activities which will continue to be administered by NIH and certain specialized training activities which will be retained by the programs to which they are closely related. The new Bureau will administer programs of school construction, student assistance and educational support. It will be involved in every stage of professional and paramedical training, including the continuing education of health personnel in practice.

The Bureau of Health Manpower will include the present Divisions of Dental Health and Nursing, plus those activities of the Divisions of Hospital and Medical Facilities and Community Health Services which relate to the development of health manpower.

C. BUREAU OF DISEASE AND INJURY PREVENTION AND CONTROL

The new Bureau of Disease and Injury Prevention and Control will consolidate the activities of the Service in preventing or controlling infectious diseases, chronic illness and disability, and accidential injury, and in controlling environmental contamination.

It will maintain surveillance of illness and deaths associated with specific diseases and conditions. It will monitor contaminants in the environment which may be harmful to health and study their relationships with morbidity and mortality. It will establish human tolerance levels for environmental contaminants and advise when such tolerances are exceeded.

The Bureau will conduct and support research directed toward improved methods for preventing and controlling disease and accidental injury. It will spearhead eradication programs and support prevention and control studies, demonstrations and programs in states and communities. It will provide technical specialists and other assistance activities for special consultant assignments to states, communities and institutions. The Bureau will develop and apply the most effective means for preventing the importation and exportation of disease and maintaining effective interstate quarantine.

The Bureau of Disease and Injury Prevention and Control will be made up of the Communicable Disease Center, the Arctic Health Research Center, the Offices of Pesticides and Solid Waste Disposal, and the Divisions of Accident Prevention, Environmental Engineering and Food Protection, Air Pollution, Occupational Health, Radiological Health and Foreign Quarantine, plus the disease control programs of the Division of Chronic Diseases.

D. NATIONAL INSTITUTE OF MENTAL HEALTH

Establishment of an expanded National Institute of Mental Health as a Bureau of the Public Health Service will give additional recognition and stimulus to the rapidly developing national program for dealing with mental illness. The problem of mental illness is particularly suited to a unified attack encompassing research, manpower training, demonstration programs and delivery of services within a single organizational component. The evolving national mental health program, stressing delivery of services in a community setting, constitutes a special system within the general health care field. It is characterized by commonality of purpose, personnel and clientele.

The National Institute of Mental Health, as a Bureau, will incorporate the present activities of the existing Institute plus the Public Health Service hospitals

for drug addiction at Lexington and Fort Worth. The intramural research activities in mental health now being conducted on the campus of the National Institutes of Health will be administered under a special relationship designed to maintain existing associations with other NIH intramural research.

Inclusion of the hospitals for drug addiction will benefit the patients of these institutions and at the same time provide the Service with clinical facilities for demonstrating new developments in the delivery of mental health care. The new mental health bureau will also serve as the principal focus for research and control programs related to alcoholism.

E. NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health will remain a bureau of the Service in parallel with the other bureaus already described. To the present structure of the Institutes will be added a National Institute of Environmental Health Sciences. The proposed Environmental Health Sciences Center to be built in North Carolina will constitute the base of the intramural research program of the new Institute, which will also administer a program of extramural grants.

The administrative framework of the National Institutes of Health provides the most appropriate and efficient setting for the major research effort urgently needed in the environmental health field. At the same time, major emphasis will be given to the development of effective bridges linking the new Institute, which represents the basic science component, with those categorical programs of the Bureau of Disease and Injury Prevention and Control which will exercise responsibility for surveillance and control of environmental hazards.

Except for this major addition and the previously described designation of the National Institute of Mental Health as an independent Bureau of the Service, the composition of the National Institutes of Health will remain essentially unchanged.

F. NATIONAL LIBRARY OF MEDICINE

The National Library of Medicine will remain in its present organizational setting and retain its existing functions including the programs initiated under the Medical Libraries Act of 1965. Consideration will be given to further strengthening and consolidating the scientific and professional communications functions of the Service, including the production and use of audiovisual materials, at a future date.

G. NATIONAL CENTER FOR HEALTH STATISTICS

The National Center for Health Statistics will remain in its present organizational setting and retain its existing functions as the principal national source of reliable statistical data related to health. Its relationship to other data-gathering units of the Service will be the object of future study.

H. OFFICE OF THE SURGEON GENERAL

To provide efficient administration for the numerous and diverse programs of the Service, the Office of the Surgeon General will be strengthened and to a certain extent reorganized. Details of this internal reorganization are now under study and will shortly be resolved.

The Office of the Surgeon General will include all the activities it now conducts, with the exception of the Division of Health Mobilization which will be located in the Bureau of Health Services. Several of these existing activities—notably those dealing with program planning and analysis, international health, scientific and public communications, and inter-agency liaison—will require substantially increased resources to deal effectively with the scope of present and projected programs.

In addition, the new system now being developed for management of grant activities will place additional central responsibilities in the Office of the Surgeon General. These will be designed to provide an organizational focus for the maintenance of uniform policies and procedures for the extramural programs of all Service components, and to establish a central point of contact and information for all PHS clientele. A coordinated means of processing statistical data will be devised to provide necessary Service-wide information to the OSG and to provide each Bureau with the information necessary to carry out its program responsibilities. Study sections and review committees will be administered at the Bureau level to assure that each Bureau receives full benefit of the scientific competence represented by these expert groups.

CONCLUSION

The rapid growth of Federal involvement in health affairs has made our present organizational structure obsolete and dictated the need for reorientation. There is every reason to expect that this involvement will continue to grow and diversify. Therefore, any structure must be adaptable to change. Flexibility is an essential ingredient.

The Public Health Service structure just described is ready for adoption. Meanwhile two proposals not included in this plan, suggested by the Corson Committee and mentioned in my January 18 memorandum, should be examined thoroughly for future consideration.

The first of these would create a bureau of the Public Health Service designed to deal comprehensively with the health problems of children. Child health is an area of great ferment. The past three years have seen the emergence of major new programs in mental retardation, the creation of an Institute of Child Health and Human Development, and the enactment of Title 19 of the Social Security Amendments with its far-reaching implications for the health of children. Still greater emphasis can be anticipated in the immediate future. I would urge, therefore, that existing organizational patterns be carefully examined in the light of changing responsibilities of the Department, looking toward a possible reorientation of the total Federal effort in the field of child health as these responsibilities become clarified.

The second of these proposals would create a Bureau of Health Systems Development to apply the systems methodology which has proved successful in other complex fields to the delivery of health services. This Bureau would have its nucleus in the regional medical programs established by the Heart Disease, Cancer and Stroke Amendments of 1965 and might eventually incorporate other Service programs. This is a challenging and promising concept. I feel, however, that the regional medical programs are well placed at the National Institutes of Health for the period of initial development, and that this organizational move should also await further study.

(Chart 1 follows:)

Appendix C

HEW Health Programs: Application Form Numbers, Matching Requirements, State Approval Requirements, Eligible Recipients, and Review Agencies

Public Health Service

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	div.	Other	
Accident prevention:										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. Division of Accident Prevention.
Fellowships	416-1	No	No					X		Community Health Research Training Committee. Division of Accident Prevention. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Community Health Research Training Committee. National Advisory Community Health Committee. Surgeon General.
Air pollution:										
Research	398, 2590	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. Division of Air Pollution (BSS). National Advisory Environmental Health Committee. Surgeon General.
Control grants	4714-1	Yes	No	X	X					Office of Program and Survey Grants (DAP). PHS Regional Office. Division of Air Pollution (BSS). Secretary, HEW.

See footnotes at end of table, p. A67.

Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Air pollution—Continued										
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. Division of Air Pollution. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Division of Air Pollution. Training Committee. National Advisory Environmental Health Committee. Surgeon General.
Survey and demonstration	4714-1	Yes	No	X	X	X				Office of Program and Survey Grants (DAP). PHS Regional Office. Division of Air Pollution (BSS). Secretary, HEW.
Allergy and infectious diseases:										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. National Advisory Allergy and Infectious Diseases Council. Surgeon General.
Gorgas Memorial Laboratory	None								Gorgas Memorial Laboratory, Panama.	National Institute of Allergy and Infectious Diseases. Surgeon General.
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Allergy and Infectious Diseases. Surgeon General.
Research career program award	2557-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Allergy and Infectious Diseases. Surgeon General.

Training	2499	No	No	X	X	X	X			Division of Research Grants. Review Committee. National Advisory Allergy and Infectious Diseases Council. Surgeon General.
Areawide health facility planning	68–R893	Yes	Yes [2]	X					Hill-Burton State agencies.	Division of Hospital and Medical Facilities. Consultants. Advisory Committee to Review Demonstration Grants. Review Committee. Federal Hospital Council. Division of Hospital and Medical Facilities. Surgeon General.
Arthritis and metabolic diseases:										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. National Institute of Arthritis and Metabolic Diseases. National Advisory Arthritis and Metabolic Diseases Council. Surgeon General.
Fellowships	416–1	No	No					X		Division of Research Grants. Review Committee. National Institute of Arthritis and Metabolic Diseases. Surgeon General.
Research career program award	2557–1	No	No					X		Division of Research Grants. Review Conmmittee. National Institute of Arthritis and Metabolic Diseases. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Training Committee (Arthritis, Dermatology, Diabetes and Metabolism, Gastroenterology and Nutrition, Hematology, Orthopedics). National Advisory Arthritis and Metabolic Diseases Council. Surgeon General.

See footnotes at end of table, p. A67.

Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Cancer:										
Formula grants [3]	Joint form 3	Yes	No	X						PHS Regional Director. Consultants. Regional Grants Management Office.
Project grants (including non-research training).	4744-1	No	Yes [4]	X	X	X	X			PHS Regional Office. Office of Grants Management.
Institutional	4744-1	No	Yes	X	X	X	X			Consultants.
Cytotechnologist	4665-1	No	Yes	X	X	X	X			Review Committee.
Traineeships	4109-1	No	Yes					X		Division of Chronic Diseases, BSS (CH). Surgeon General.
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. National Cancer Institute. National Advisory Cancer Council. Surgeon General.
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. National Cancer Institute. Surgeon General.
Research career program award	2557-1	No	No					X		Division of Research Grants. Review Committee. National Cancer Institute. Surgeon General.
Training (to be replaced fiscal year 1967 by clinical cancer training program).	2499	No	No	X	X	X	X			Division of Research Grants. Study sections. National Advisory Cancer Council. Surgeon General.
Cerebrovascular disease (see also Heart disease):										
Clinical traineeships (NHI)	1891	No	No					X		National Heart Institute. Training Committee. Surgeon General.

Clinical traineeships (NINDB)	1891	No	No					X		National Institute of Neurological Diseases and Blindness. Training Committee. Surgeon General.
Training (NHI)	2499	No	No			X	X			Division of Research Grants. National Heart Institute Training Committee. National Advisory Heart Council. Surgeon General.
Training (NINDB)	2499	No	No			X	X			Division of Research Grants. National Institute of Neurological Diseases and Blindness Training Grant Committee. National Advisory Neurological Diseases and Blindness Council. Surgeon General.
Child health and human development:										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. National Institute of Child Health and Human Development. National Advisory Child Health and Human Development Council. Surgeon General.
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Child Health and Human Development. Surgeon General.
Research career program award	2557-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Child Health and Human Development. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Training Committee (Aging, Child Development and Mental Retardation, Reproduction). National Advisory Child Health and Human Development Council. Surgeon General.

See footnotes at end of table, p. A67.

Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Chronic diseases:										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. Division of Chronic Diseases (BSS-CH). National Advisory Community Health Committee. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Community Health Research Training Committee. National Advisory Community Health Committee. Surgeon General.
Chronic illness and aged:										
Formula grants [3]	Joint form 3	Yes	No	X						PHS Regional Director. Consultants. Regional Grants Management Office.
Clinical cancer training. (See Cancer training.)										
Communicable diseases:										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. Communicable Disease Center. National Advisory Community Health Committee. Surgeon General.
Community health:										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. Division of Community Health Services. National Advisory Community Health Committee. Surgeon General.

Fellowships	416–1	No	No					X		Division of Research Grants. Review Committee. Community Health Research Training Committee. Division of Community Health Services. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Community Health Research Training Committee. National Advisory Community Health Committee. Surgeon General.
Community Health Services (Chronically Ill and Aged)	4744–1	No	Yes	X	X	X	X			Bureau of State Services, Community Health Divisions. Surgeon General.
Community mental health centers:										
Construction	62–1 through 62–8.	Yes	Yes	X	X	X				Mental health program staff or PHS Regional Office. National Institute of Mental Health. Surgeon General.
Initial staffing	In preparation.	Yes	Yes	X	X	X				National Institute of Mental Health. Secretary, HEW.
Dental health:										
Formula grants [3]	Joint form 3	Yes	Yes	X						PHS Regional Director. Consultants. Regional Grants Management Office.
Research (BSS)	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. Division of Dental Health. National Advisory Community Health Committee. Surgeon General.
Research (NIH)	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. National Institute of Dental Research. National Advisory Dental Research Council. Surgeon General.

See footnotes at end of table, p. A67.

Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Dental health—Continued										
Training (BSS) (auxiliary utilization training).	2499	No	No				X			Division of Research Grants. Advisory Committee on Dental Student Training. Division of Dental Health. Surgeon General.
Research training (NIH)	2499	No	No	X	X	X	X			Division of Research Grants. Dental Training Committee. National Institute of Dental Research. National Advisory Dental Research Council. Surgeon General.
Research training (BSS)	2499	No	No	X	X	X	X			Division of Research Grants. Community Health Research Training Committee. National Advisory Community Health Committee. Surgeon General.
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Dental Research. Surgeon General.
Research career program award	2557-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Dental Research. Surgeon General.
Educational improvement grants to schools of medicine, dentistry, osteopathy, optometry, and podiatry.	T-343-1	No	No				X			Training Resources Branch, Division of Community Health Services. Division of Dental Health (for dental). National Advisory Council on Medical, Dental, Optometric, and Podiatric Education. Division of Community Health Services. Surgeon General.

Environmental engineering and food protection:										
Research	398, 2590	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Division of Environmental Engineering and Food Protection Study Sections. National Advisory Environmental Health Committee. Surgeon General.
Environmental health sciences:										
Research	398, 2590	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Office of Resources Development. Study sections. National Advisory Environmental Health Committee. Surgeon General.
Research training	2499	No	No			X	X	X		Division of Research Grants. Environmental Sciences Training Committee. National Advisory Environmental Health Committee. Surgeon General.
General clinical research centers	398	No	No			X	X			General Clinical Research Center Committee. National Advisory Research Resources Committee. Surgeon General.
General health:										
Formula grants [3]	Joint form 3	Yes	Yes	X						PHS Regional Director. Consultants. Regional Grants Management Office.
General medical sciences:										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. National Institute of General Medical Sciences. Study sections. National Advisory General Medical Sciences Council. Surgeon General.
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. National Institute of General Medical Sciences. Surgeon General.

See footnotes at end of table, p.

Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
General medical sciences—Con.										
Research career program award	2557-1	No	No					X		Division of Research Grants. Review Committee. National Institute of General Medical Sciences. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. National Institute of General Medical Sciences. Review committees. National Advisory General Medical Sciences Council. Surgeon General.
General research support	NIH-147-1	No	No [5]	X	X	X	X			General Research Support Scientific Advisory and Review Committee. National Advisory Health Council. Surgeon General.
Gorgas Memorial Laboratory. (See National Institute of Allergy and Infectious Diseases.)										
Hawaii leprosy payment	None								State of Hawaii, Department of Health.	Division of Hospitals. Surgeon General.
Health professions educational facilities construction.	4687	Yes	Yes				X		Affiliated hospitals	Review Committee. National Advisory Council on Education for Health Professions. Surgeon General.
Health professions student loan program:										
Initial application	4663-1	Yes	No				X			Training Resources Branch, Division of Community Health Services.
Annual allocation	4663-2	Yes	No				X			Division of Community Health Services. Surgeon General.
Health research facilities construction:										
Single grant	4377	Yes	No	X	X	X	X		Research centers	Division of Research Facilities and Resources, NIH.

Joint grant	4687	Yes	No	X	X	X	X		Research centers	Scientific Review Committee. National Advisory Council for Health Research Facilities and Resources. Surgeon General.
Heart disease (see also Cerebrovascular disease):										
Formula grants [3]	Joint form 3	Yes	Yes	X						PHS Regional Director. Consultants. Regional Grants Management Office.
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. National Heart Institute. National Advisory Heart Council. Surgeon General.
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. National Heart Institute. Surgeon General.
Research career program award	2557-1	No	No					X		Division of Research Grants. Review Committee. National Heart Institute. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Heart Training Committee. National Advisory Heart Council.
Graduate clinical training (NHI) (in preparation).										Surgeon General.
Home health services:										
Formula grants.[3]	Joint form 3	Yes	Yes	X						PHS Regional Director. Consultants. Regional Grants Management Office.
Hospital and medical facilities construction (see also Areawide health facility planning).	62-1 through 62-8.	Yes	Yes	X	X	X	X			PHS Regional Office. HEW Regional Director. Surgeon General.
Immunization project grants	4744-1	No	Yes	X	X					PHS Regional Office. Office of Grants Management. Communicable Disease Center. Surgeon General.
International centers for medical research and training.	398	No	No				X			Office of International Research Advisory Review Committee. National Advisory Health Council. Surgeon General.

See footnotes at end of table, p. A67.

Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
International grants and awards:										
International postdoctoral fellowships.	416-1	No	No					X	Only nonimmigrant aliens or foreign biomedical students.	Review Committee. National Institutes of Health. International Fellowship Review Committee. Surgeon General.
PHS fellows in foreign laboratories.	416-1	No	No					X		Division of Research Grants. Review Committee. Appropriate institute or division of PHS. Surgeon General.
Training grants, traineeships	2499	No	No				X		Only foreign research centers.	Division of Research Grants. Appropriate institute or division of PHS. Review Committee. Appropriate advisory council or committee. Surgeon General.
Visiting program	None	No	No					X	Only by invitation	National Institutes of Health.
Research grants (foreign)	398	No	No			X	X	X		Division of Research Grants. Appropriate institute or division of PHS. Study sections. Appropriate advisory council or committee. Surgeon General.
Research contracts (foreign)	None	No	No			X	X	X	Any qualified responsible contractor.	National Institutes of Health.
International medical research studies, translations—Foreign currency program.	None	No	No			X	X	X	Only foreign scientists and institutions.	Consultants. National Library of Medicine. Surgeon General.
Medical facilities construction. (See Hospital and medical facilities construction.)										

Research	398	No	No	X	X	X	X	X		Division of Research Grants. Study sections. National Library of Medicine Board of Regents Advisory Committee for Extramural Programs. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Review committees. National Library of Medicine Board of Regents Advisory Committee for Extramural Programs. Surgeon General.
Fellowships	416	No	No	X	X	X	X	X		Division of Research Grants. Review Committee. National Library of Medicine. Surgeon General.
Publications	398	No	No	X	X	X	X	X		Division of Research Grants. Study sections. National Library of Medicine Board of Regents Advisory Committee for Extramural Programs. Surgeon General.
Resources	4877	No	No	X	X	X	X			Division of Research Grants. National Library of Medicine. Surgeon General.
Special scientific projects (in preparation).	416	No	No	X	X	X	X	X		Division of Research Grants. Review committees. National Library of Medicine. Surgeon General.
Construction grants (in preparation).		Yes	No	X	X	X	X			In preparation.
Establishment of regional medical libraries (in preparation).		Yes	No	X	X	X	X			In preparation.
Mental health:										
Formula grants [3]	Joint form 3	Yes	No	X						PHS Regional Director. Consultants. Regional Grants Management Office.
Hospital improvement	2697	No	Yes	X						National Institute of Mental Health. Review Committee. National Advisory Mental Health Council. Surgeon General.

See footnotes at end of table, p. A67.

Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Mental health—Continued										
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Study sections. National Institute of Mental Health. National Advisory Mental Health Council. Surgeon General.
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Mental Health. Surgeon General.
Research career program award	416-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Mental Health. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Review Committee. National Institute of Mental Health. National Advisory Mental Health Council. Surgeon General.
Mental retardation:										
Implementation project grants	4744-1	Yes	Yes	X						PHS Regional Office. Review Committee. Division of Chronic Diseases. Surgeon General.
Project grants	4744-1	No	No [6]	X	X	X	X			Office of Grants Management. Review Committee. Division of Chronic Diseases. Surgeon General.
Project grants for training	4744-1	No	No	X	X	X	X	X		Office of Grants Management. Division of Chronic Diseases. Consultants. Review Committee. Surgeon General.

Mental retardation facilities construction:										
Research centers	4687	Yes	No	X	X	X	X			Division of Research Grants. Division of Research Facilities and Resources. National Institute of Child Health and Human Development. Health Research Facilities Scientific Review Committee. National Advisory Council on Health Research Facilities. National Advisory Child Health and Human Development Council. Surgeon General.
Clinical facilities (university affiliated).	4687	Yes	No	X	X	X	X		Only if affiliated with university or college.	Division of Research Grants. Division of Hospital and Medical Facilities (BSS). Consultants. Subcommittee on Construction of University Affiliated Facilities for the Mentally Retarded. Surgeon General.
Facilities for mentally retarded	62-1 through 62-8.	Yes	Yes	X	X	X	X			HEW Regional Office Division of Hospital and Medical Facilities. Review Committee. Surgeon General.
Migrant health	4744-1	Yes	Yes	X	X	X	X		No State OK if from regional or national agency.	Office of Grants Management. Migrant Health Branch (DCHS). Review Committee. Division of Community Health Services. Surgeon General.
National Heart Institute:										
Graduate clinical training. (See Heart disease.)										
National primate research centers	None								No further applications accepted at this time.	None.
Neurological and sensory diseases (see also Cerebrovascular diseases):										
Project	4744-1	No	Yes	X	X	X	X		No state OK if from national agency.	Office of Grants Management. Review Committee. Division of Chronic Diseases. Surgeon General.

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Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Neurological and sensory diseases—Continued										
Service training	4744-1	No	No	X	X	X	X	X		Office of Grants Management. Division of Chronic Diseases. Consultants. Review Committee. Division of Chronic Diseases. Surgeon General.
Research	398	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. National Institute of Neurological Diseases and Blindness. Study sections. National Advisory Neurological Diseases and Blindness Council. Surgeon General.
Direct traineeships	In preparation.	No	No					X		Division of Research Grants. National Institute of Neurological Diseases and Blindness. Review committees. Surgeon General.
Fellowships	416-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Neurological Diseases and Blindness. Surgeon General.
Research career program award	2557-1	No	No					X		Division of Research Grants. Review Committee. National Institute of Neurological Diseases and Blindness. Surgeon General.
Training	2499	No	No	X	X	X	X			Division of Research Grants. Review Committee. National Institute of Neurological Diseases and Blindness. National Advisory Neurological Diseases and Blindness Council. Surgeon General.

Research	398	Cost sharing.	No	X	X	X	X	X			Division of Research Grants. Study sections. Division of Nursing. National Advisory Community Health Committee. Surgeon General.
Fellowships	416-1	No	No					X			Nurse Scientist Graduate Training Committee. Review Committee. Division of Nursing. Surgeon General.
Professional traineeships:											
Short term	3190-10	No	No					X			Division of Nursing. Office of Grants Management. Review Committee. Surgeon General.
Long term	3190-5	No	No					X			Division of Nursing. Division of Nursing Personnel. Surgeon General.
Nurse-scientist graduate training	2499	No	No				X				Division of Research Grants. National Scientist Graduate Training Committee. National Advisory Community Health Committee. Surgeon General.
Diploma schools	4782-1	No	No				X				Division of Nursing. Surgeon General.
Loans to students	4755-2	Yes	No				X	X			Training Resources Branch, DCHS. Division of Community Health Services. Surgeon General.
Projects for improvement	478-1	No	No			X	X				Division of Nursing. Office of Grants Management. Review Committee. National Advisory Council on Nurse Training. Surgeon General.
Construction	4687-1 through 4687-5.	Yes	No				X				Division of Research Grants. Division of Nursing. Review Committee. National Advisory Council on Nurse Training. Surgeon General.

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Public Health Service—Continued

Program	PHS form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Occupational health:										
Research	398, 2590	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Division of Occupational Health. Study sections. National Advisory Environmental Health Committee. Surgeon General.
Public health:										
Graduate training	4744-1	No	No				X			Training Resources Branch, DCHS. National Advisory Committee on Public Health Training. Surgeon General.
Traineeships	2629	No	No					X		Training Resources Branch, DCHS.
Institutions	2630	No	No				X			Consultants. National Advisory Committee on Public Health Training. Division of Community Health Services. Surgeon General.
Schools of public health	3505	No	No				X			Bureau of State Services. Division of Community Health Services. Surgeon General.
Radiological health:										
Formula grants [3]	Joint form 3	Yes	Yes	X						PHS Regional Director. Consultants. Regional Grants Management Office.
Research	398, 2590	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Division of Radiological Health. Study sections. National Advisory Environmental Health Committee. Surgeon General.
Training	3582	No	No				X			Division of Radiological Health. Committee on Radiation Health Training Grants. Surgeon General.
Regional medical programs (heart disease, cancer, stroke).	NIH-925	Yes	No	X	X	X	X			Division of Regional Medical Programs. Consultants. National Advisory Committee on Regional Medical Programs.
Research contracts, NIH	None	No	No	X	X	X	X	X	Any qualified responsible contractor.	National Institutes of Health.

Research contracts, NIH	None	No	No	X	X	X	X	X	Any qualified responsible contractor.	National Institutes of Health.
Scholarship grants to schools of medicine, dentistry, osteopathy, optometry, podiatry or pharmacy.	T-344-1	No	No				X			Training Resources Branch, Division of Community Health Services. National Advisory Council on Medical, Dental, Optometric, and Podiatric Education. Surgeon General.
Solid waste disposal:										
Demonstration studies and investigation grants.	In preparation.	Yes	No	X	X	X	X			In preparation.
Planning	do	Yes	Yes	X					Also interstate agencies	Do.
Research	398, 2590	Cost sharing.	No	X	X	X	X	X		Division of Research Grants. Office of Solid Wastes. Study sections. National Advisory Environmental Health Committee. Surgeon General.
Training	2499	Cost sharing.	No	X	X	X	X			Division of Research Grants. Office of Solid Waste Disposal. Environmental Science Training Committee. National Advisory Environmental Health Committee. Surgeon General.
Special research resources (see also National primate research centers).	398, 2590	No	No			X	X			Division of Research Grants. National Institutes of Health. Consultants. National Advisory Research Resources Committee. Surgeon General.
Tuberculosis control:										
Formula grants [3]	Joint form 3	Yes	Yes	X						PHS Regional Director. Consultants. Regional Grants Management Office.
Project grants	4744-1	No	Yes	X	X					PHS Regional Office. Office of Grants Management. Communicable Disease Center. Surgeon General.
Venereal disease control	4744-1	No	No	X	X					PHS Regional Office. Office of Grants Management. Communicable Disease Center. Surgeon General.

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Vocational Rehabilitation Administration

Program	VRA form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Basic support grants (formula)	A-1	Yes	Yes	X						VRA regional staff. Division of State Plans, Projects, and Grants. Assistant Commissioner, Program Services.
Innovation grants (formula for projects within States).	A-7	Yes	Yes	X						VRA regional staff. Division of State Plans, Projects, and Grants. Assistant Commissioner, Program Services.
Expansion grants:										
(Applic.)	A-8	Yes	Yes	X	X	X				VRA regional staff. Division of State Plans, Projects, and Grants. Assistant Commissioner, Program Services.
(Budget)	A-9									
Statewide planning grants (project)	23	No	Yes [7]	X						VRA regional staff. Division of State Program Administration. Assistant Commissioner, Program Services. Commissioner, VRA.
Provision of vocational rehabilitation services for social security beneficiaries paid for out of trust funds (general support).	In preparation.	No	Yes	X						Procedure in preparation.
Project grants and assistance for workshops and rehabilitation facilities:										
State planning grants	26	Yes	Yes	X						VRA regional staff. Division of Rehabilitation Facilities and Workshops. Assistant Commissioner, Program Services.

Project development grants	27	Yes	Yes	X	X	X				VRA regional staff. Division of Rehabilitation Facilities and Workshops. Assistant Commissioner, Program Services.
Construction grants	33	Yes	Yes	X	X	X				VRA regional staff. Division of Rehabilitation Facilities and Workshops. Assistant Commissioner, Program Services.
Initial staffing grants (project)	In preparation	Yes	Yes	X	X	X				VRA regional staff. Division of Rehabilitation Facilities and Workshops. Assistant Commissioner, Program Services.
Workshop improvement grants (project).	25	Yes	Yes	X	X	X				VRA regional staff. Division of Rehabilitation Facilities and Workshops. Assistant Commissioner, Program Services.
Grants for projects for training services.	In preparation	Yes	(8)	X	X	X				Procedure in preparation.
Research and demonstration	3	Yes	(9)	X	X	X	X			Division of Research and Demonstrations. Study Section. National Advisory Council on Vocational Rehabilitation. Commissioner, VRA.
Research and training centers	3	Yes	(8)	X	X	X	X			Division of Research and Training Centers. Study Committee. National Advisory Council on Vocational Rehabilitation. Commissioner, VRA.

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Vocational Rehabilitation Administration—Continued

Program	VRA form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Training and traineeships:										
Sec. 4 grants	7	Yes	(9)	X	X	X	X			Division of Training. Consultants. Advisory training panels. Assistant Comissioner, Research and Training.
Sec. 7 contracts	Letter	No	(9)	X	X	X	X		Profitmaking and nonprofit agencies.	Division of Training. Committee on Short-Term Training. VRA regional staff. Assistant Commissioner, Research and Training.
Research fellowships	14	No	(9)					X		Division of Research and Demonstrations. Research Fellowship Board. Assistant Commissioner, Research and Training.
Traineeships	9	No	(9)					X		Division of Training. Consultants. Advisory training panels. Assistant Commissioner, Research and Training.
International rehabilitation—Research and training—Foreign currency program.		No	No						Governmental and other nonprofit organizations in participating countries.	Division of International Rehabilitation Activities. Consultants and special committees. Assistant Commissioner, Research and Training. Commissioner, VRA.
Correctional Rehabilitation Study Act grants.	3	Yes	No			X			Nonogovernmental agencies, organizations, or commissions.	Assistant Commissioner, Research and Training. Consultants. National Advisory Commission on Correctional Manpower and Training.

Program	WA form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Maternal and child health:										
Formula	None	Yes	Yes	X						(A) HEW Regional Office. Division of Health Services (CB). Chief, Children's Bureau. Secretary, HEW.
Project	do	No	No	X			X			(B) Division of Health Services (CB). Chief, Children's Bureau. Secretary, HEW.
Crippled children:										
Formula	do	Yes	Yes	X						Same as (A) above.
Project	do	No	No	X			X			Same as (B) above.
Maternity and infant care—Special project grants.	40, 41	Yes	Yes	X	X		X		X	Do.
Health of school and preschool children—Special project grants.	50, 51	Yes	Yes	X	X					Do.
Training grants	None	No	No	X			X			Same as (B) above; also reviewed by outside consultants.
Research grants	CB-MCH-CCR-1.	No	No	X	X	X	X			Division of Research. Consultants. Advisory Group. Chief, Children's Bureau. Secretary, HEW.
Old-age assistance	None	Yes	Yes	X						HEW Regional Office. Bureau of Family Services. Commissioner, WA. Secretary, HEW.
Medical assistance for the aged	do	Yes	Yes	X						HEW Regional Office. Bureau of Family Services. Commissioner, WA. Secretary, HEW.

See footnotes at end of table, p. A67.

Welfare Administration—Continued

Program	WA form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Aid to families with dependent children.	do	Yes	Yes	X						[10].
Aid to blind	do	Yes	Yes	X						[10].
Aid to permanently and totally disabled.	do	Yes	Yes	X						[10].
Aid to the aged, blind, or disabled or such aid and medical assistance for the aged.	do	Yes	Yes	X						[10].
Medical assistance program	do	Yes	Yes	X						[10].
Repatriates	do	No	No	X						[11].

Office of Education

Program	OE form No.	Matching funds required	State OK required	Eligible recipients [1]						Review agencies
				State	Local	PNP	Educ.	Indiv.	Other	
Vocational and technical education:										
State allotment programs	None	Yes	Yes	X						Division of Vocational and Technical Education, Bureau of Adult Vocational Education. Advisory councils. Commissioner of Education.
Research, training, and development programs.	do	Yes	Yes	X	X	X	X			Division of Adult and Vocational Research, Bureau of Research. Advisory Council. Commissioner of Education.

Residential school programs	do	Yes	Yes	X	X	X	X			Division of Vocational and Technical Education, Bureau of Adult Vocational Education. Commissioner of Education.
Elementary and secondary education:										
Title I—Educationally deprived children.	do	No	Yes		X					Division of Program Operations, Bureau of Elementary and Secondary Education. Advisory Council. Commissioner of Education.
Title III—Supplementary centers services:										
Planning	4312	No	Yes		X					Division of Plans and Supplementary Services, Bureau of Elementary and Secondary Education. Advisory Council. Commissioner of Education.
Operational	4313	No	Yes		X					Division of Plans and Supplementary Services, Bureau of Elementary and Secondary Education. Advisory Council. Commissioner of Education.
Title V—State leadership	5168 5169 5170 5172	(12)	Yes	X						Division of State Agency Cooperation, Bureau of Secondary Education. Advisory Council. Commissioner of Education.

[1] Eligible recipients: State—State governmental agency. Local—Local governmental agency. PNP—Private nonprofit organization or institution. Educ.—Educational institution. Indiv.—Individual.

[2] The State health department is notified when a grant is made except in 4 States where State health department is not the agency designated to administer or supervise the administration of the Hill-Burton program.

[3] Formula grant: State plan required; submited to Office of Grants Management (BSS). State health departments submit the State plan for all formula grants, except in those instances in which State agencies other than health departments have been designated to administer cancer control and mental health grant programs. The State health department or mental health agency is notified by letter from the PHS regional health director when a State plan, budget, or revision of either, is approved.

[4] State review required.

[5] State OK required if State health department is recipient.

[6] State is informed.

[7] State planning agency designated by Governor.

[8] To be determined.

[9] State approval required if direct services are provided to handicapped individuals.

[10] All of the grants are formula grants (which include vendor payments to providers of health services) made on the basis of plans submitted by the States to HEW regional offices, where they are reviewed by the Bureau of Family Services. The Division of Program Operations of the Bureau is responsible for their review in Washington. They are then approved by the Commissioner of Welfare under delegation from the Secretary of HEW.

[11] Represents reimbursements to States for expenditures made in accordance with agreements.

[12] No matching funds required for fiscal years 1966, 1967.

Appendix D

HEW Health Programs: Summary of Eligible Recipients

The following charts and tables indicate the eligible recipients for grants and awards provided by the operating agencies of the Department, and the number of programs for which each is eligible, as classified by the following six types of programs:

1. Research.
2. Training.
3. Services (Formula).
4. Services (Project).
5. Planning.
6. Construction.

It should be noted that some programs fit properly into several classifications. Also, certain programs do not fit precisely into any one of these categories, but are listed here under that category which is most nearly appropriate.

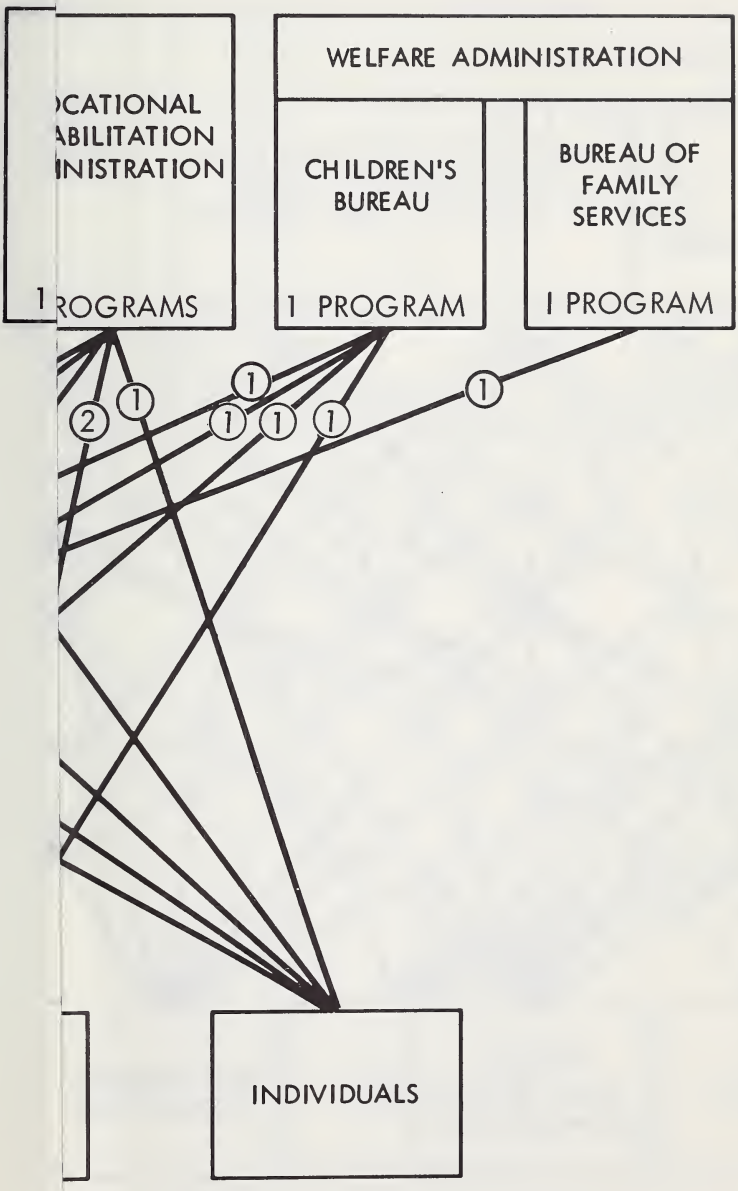
The eligible recipents shown here include State governmental agencies, local governmental agencies, private non-profit organizations, educational institutions, and individuals. Other eligible recipients—for example, foreign research centers—which may be involved in a limited number of programs are not included in this section.

Research

	State	Local	PNP	Educ.	Indiv.
PUBLIC HEALTH SERVICE					
Bureau of State Services (Community Health):					
Accident prevention	X	X	X	X	X
Chronic diseases	X	X	X	X	X
Communicable diseases	X	X	X	X	X
Community health	X	X	X	X	X
Community health services (chronically ill and aged)	X	X	X	X	
Dental health	X	X	X	X	X
International grants and awards			X	X	X
Nursing	X	X	X	X	X
Total (8)	7	7	8	8	7
Bureau of State Services (Environmental Health):					
Air pollution	X	X	X	X	X
Environmental engineering and food protection	X	X	X	X	X
Environmental health sciences	X	X	X	X	X
International grants and awards			X	X	X
Occupational health	X	X	X	X	X
Radiological health	X	X	X	X	X
Solid waste disposal	X	X	X	X	X
Total (7)	6	6	7	7	7
National Institutes of Health:					
Allergy	X	X	X	X	X
Arthritis	X	X	X	X	X
Cancer	X	X	X	X	X
Child health and human development	X	X	X	X	X
Dental health	X	X	X	X	X
General clinical research centers			X	X	
General medical sciences	X	X	X	X	X
General research support	X	X	X	X	
Heart disease	X	X	X	X	X
International centers for medical research and training				X	
International grants and awards:					
Research grants			X	X	X
Research contracts			X	X	X
International medical research studies			X	X	X
Mental health	X	X	X	X	X
National primate research centers (no applications accepted at this time)					
Neurological and sensory diseases	X	X	X	X	X
Research contracts	X	X	X	X	X
Special research resources			X	X	
Total (18)	11	11	16	17	13

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CONTRACTS

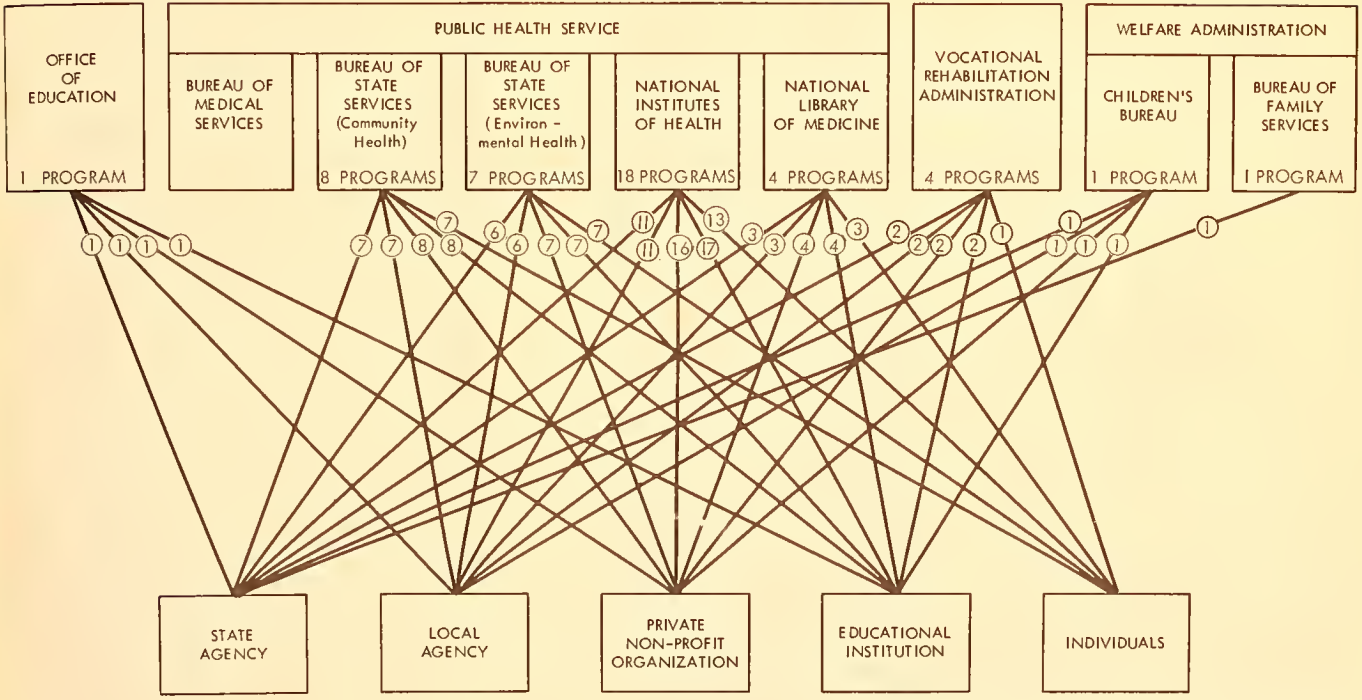


OF PROGRAMS FOR WHICH RECIPIENT IS ELIGIBLE

70-135 O - 66 (Face p. A68) No. 1

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ELIGIBLE RECIPIENTS OF GRANTS AND CONTRACTS
—RESEARCH —



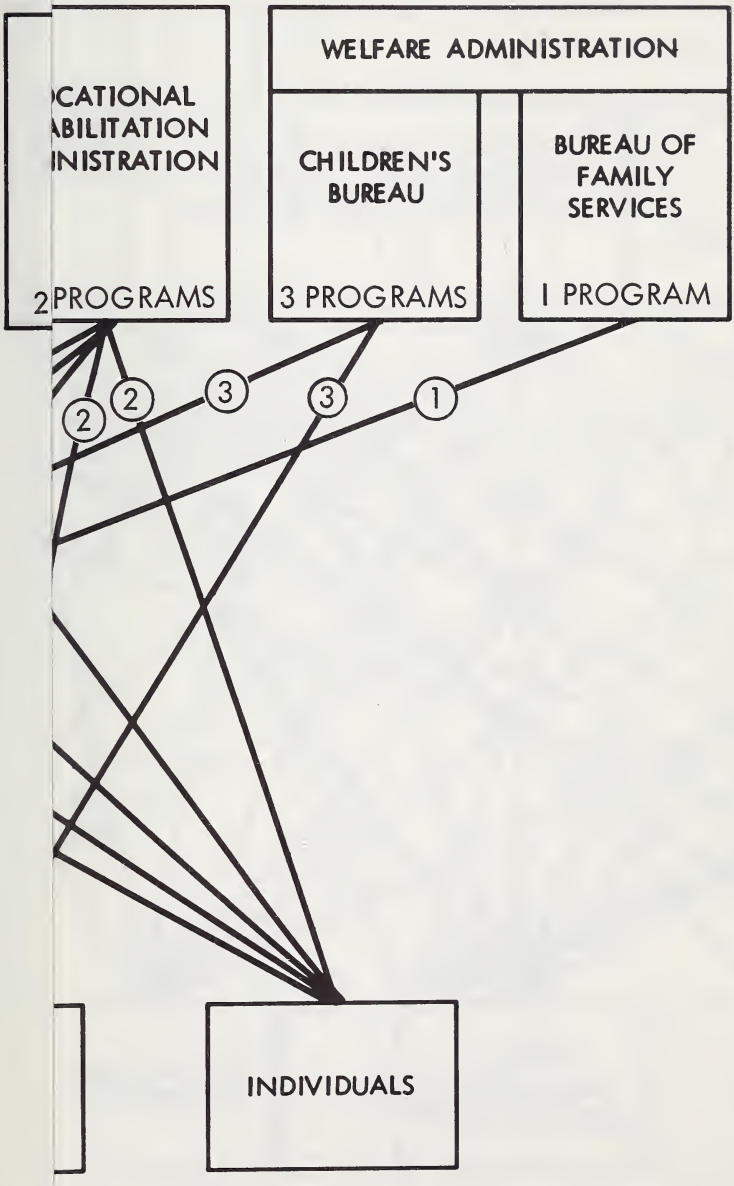
(2) NUMBER OF PROGRAMS FOR WHICH RECIPIENT IS ELIGIBLE

70-135 O - 70 (Face p. A168) No. 1



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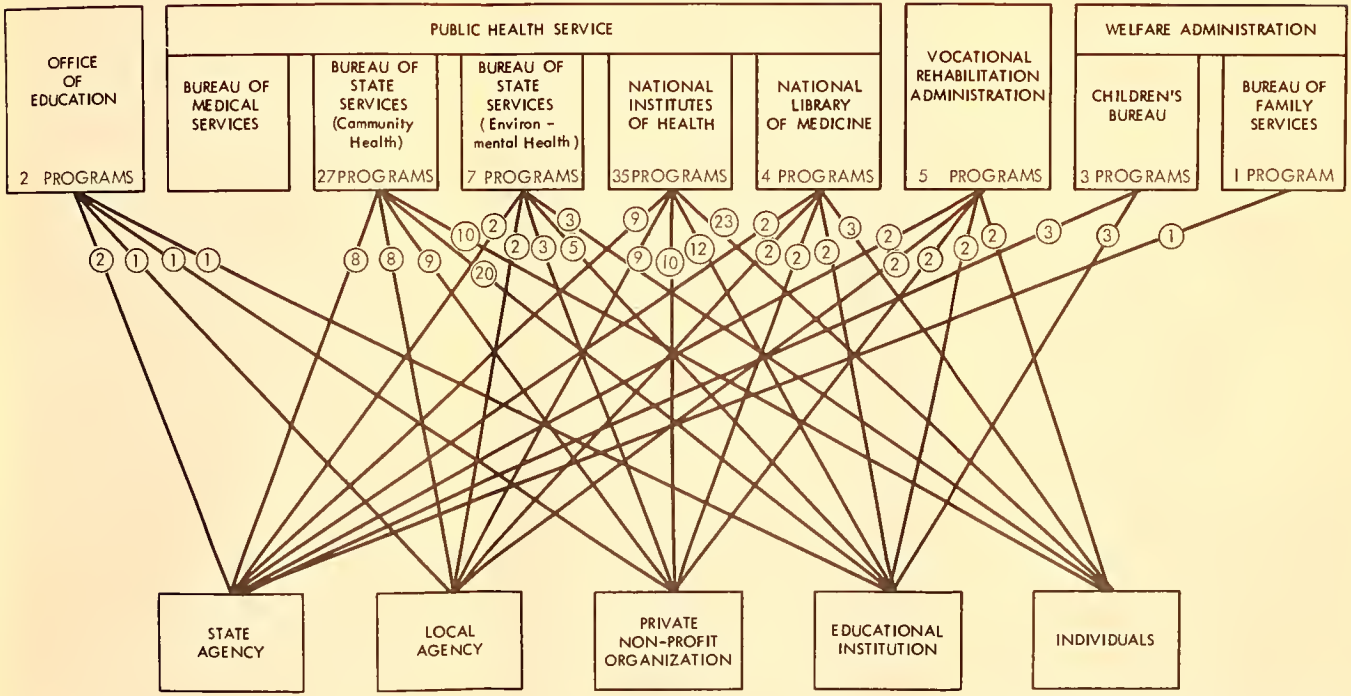
OF PROGRAMS FOR WHICH RECIPIENT IS ELIGIBLE

70-135 O - 66 (Face p. A68) No. 2



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ELIGIBLE RECIPIENTS OF GRANTS AND CONTRACTS
— TRAINING —



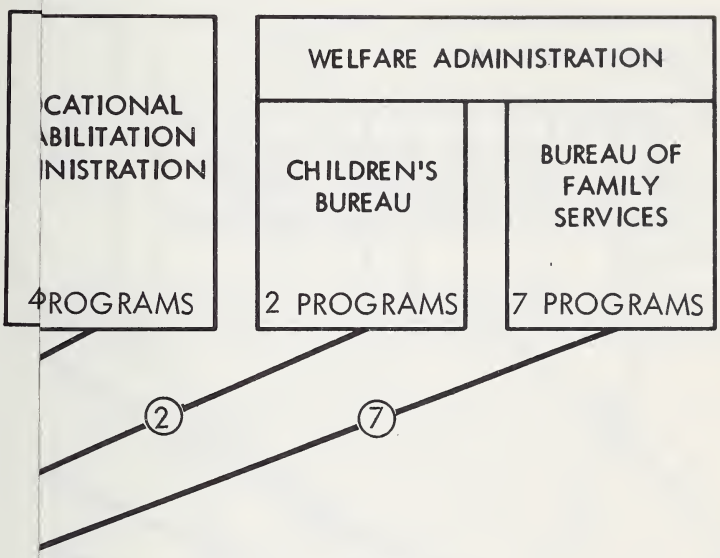
(2) NUMBER OF PROGRAMS FOR WHICH RECIPIENT IS ELIGIBLE

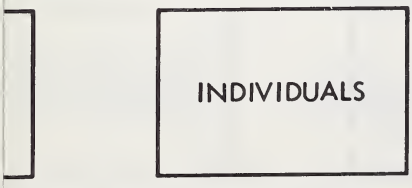
70-135 O - 68 (Face p. A68) No. 2



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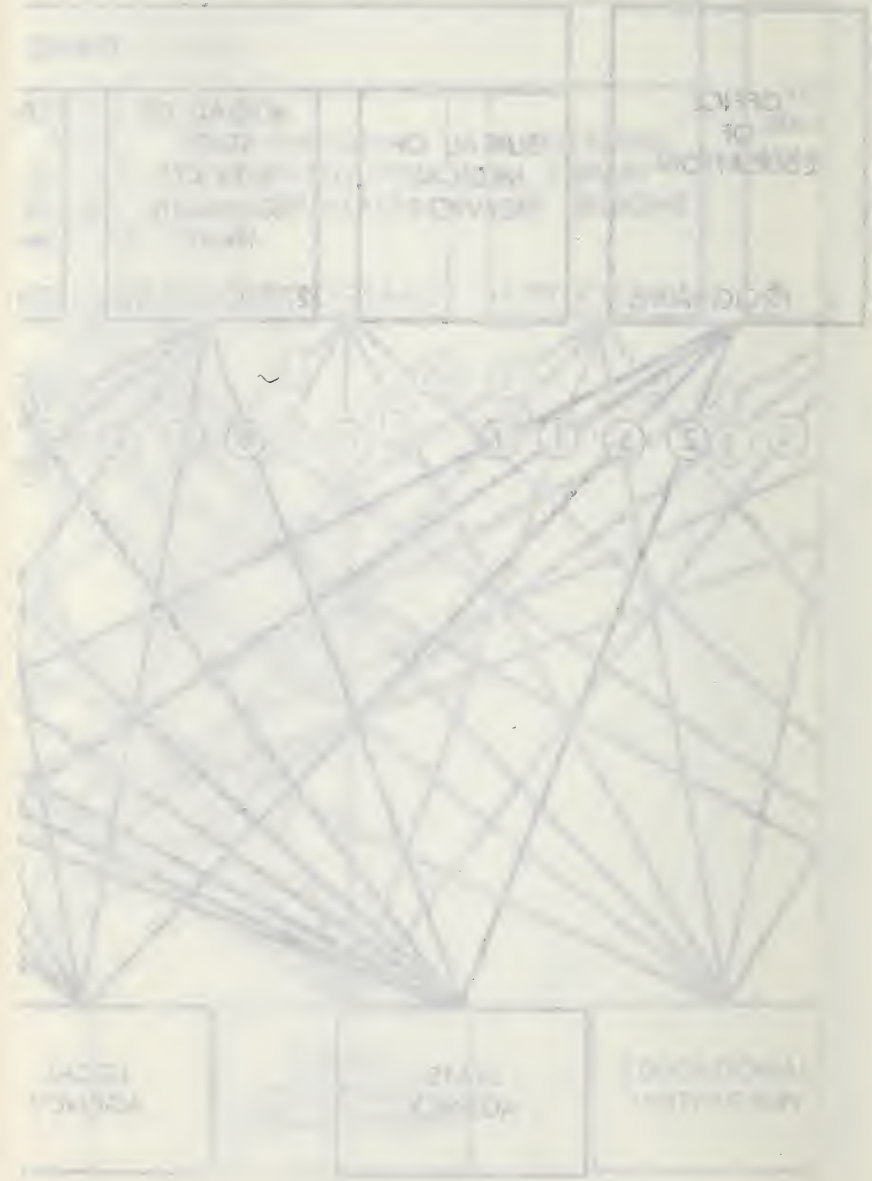
AWARDS





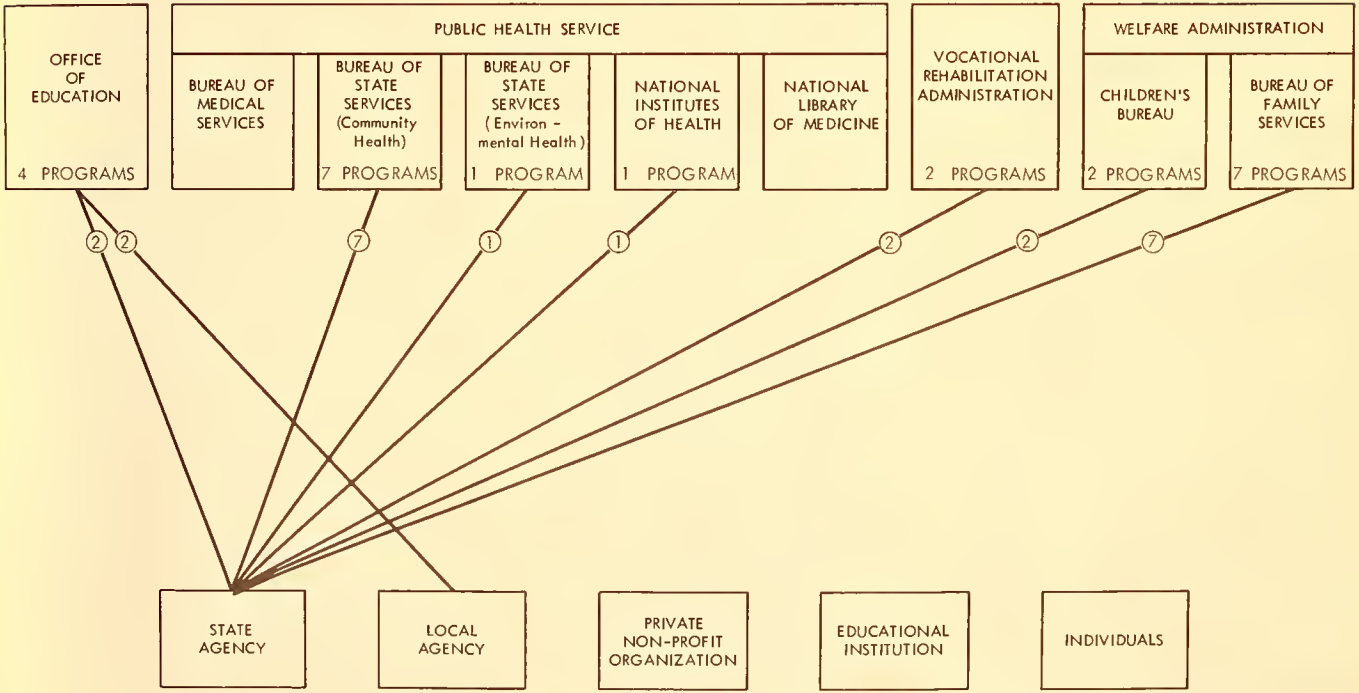
OF PROGRAMS FOR WHICH RECIPIENT IS ELIGIBLE

70-135 O - 66 (Face p. A68) No. 3



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ELIGIBLE RECIPIENTS OF GRANTS AND AWARDS
— SERVICES (FORMULA) —

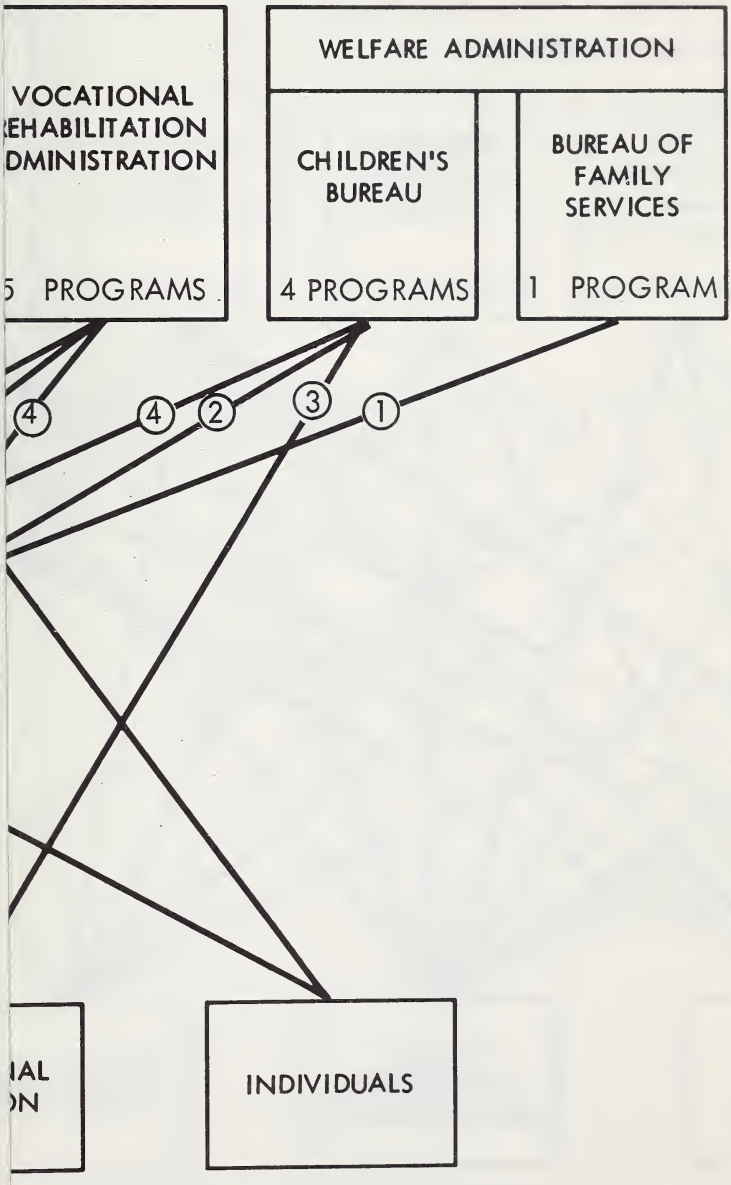


(2) NUMBER OF PROGRAMS FOR WHICH RECIPIENT IS ELIGIBLE

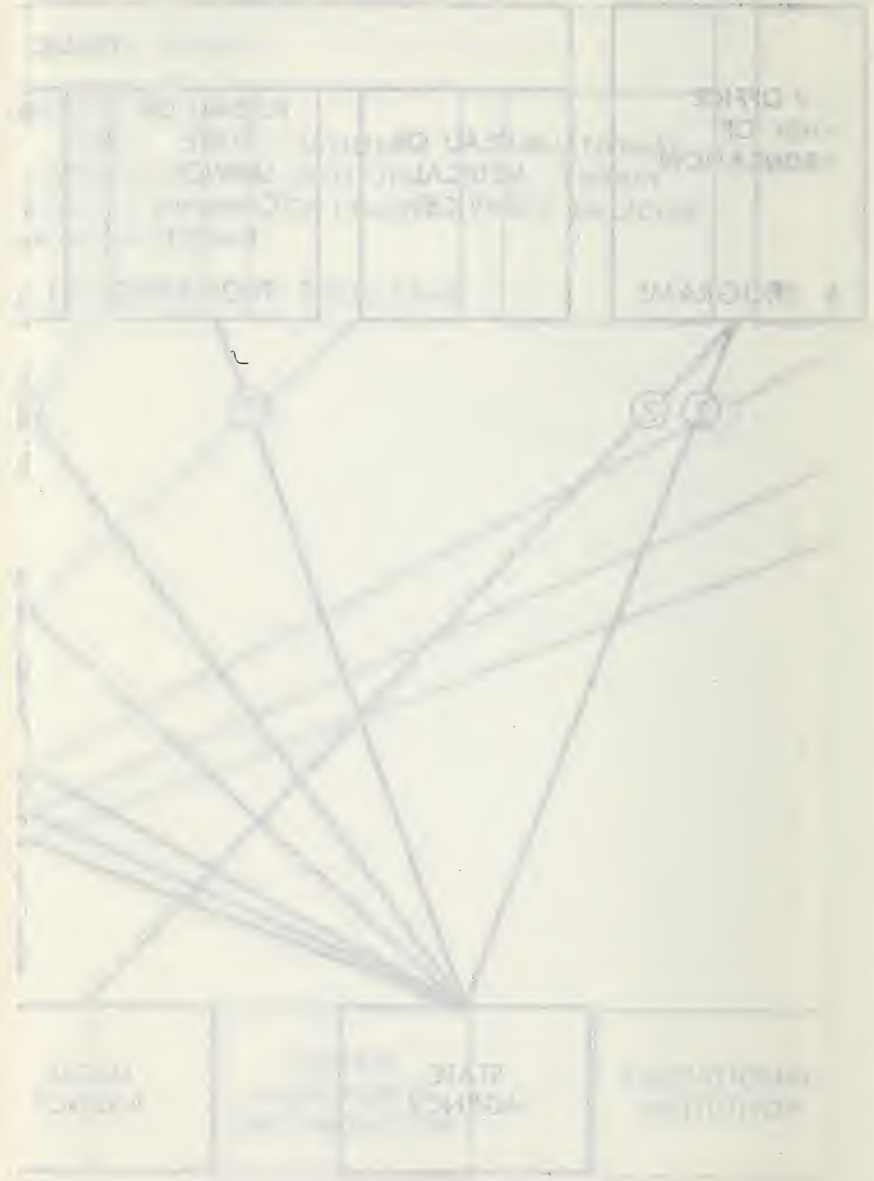
70-135 O - 66 (Face p. A68) No. 3



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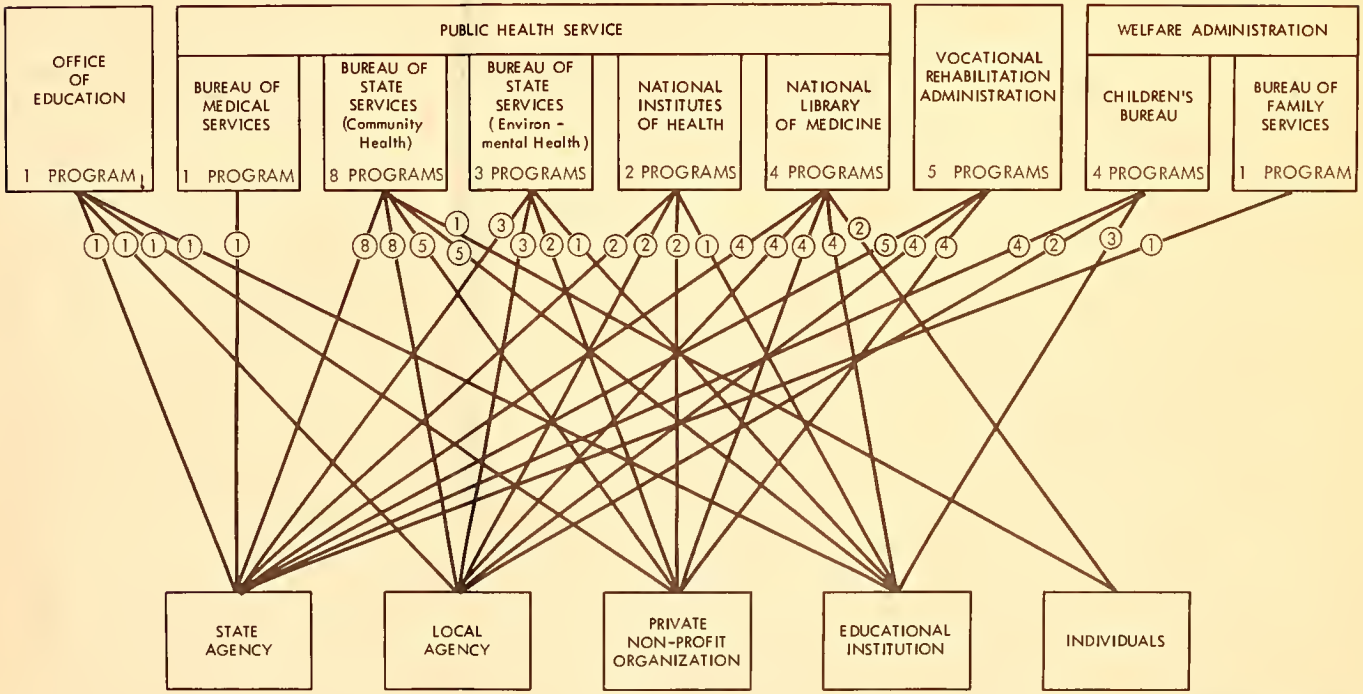


70-135 O - 66 (Face p. A68) No. 4



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

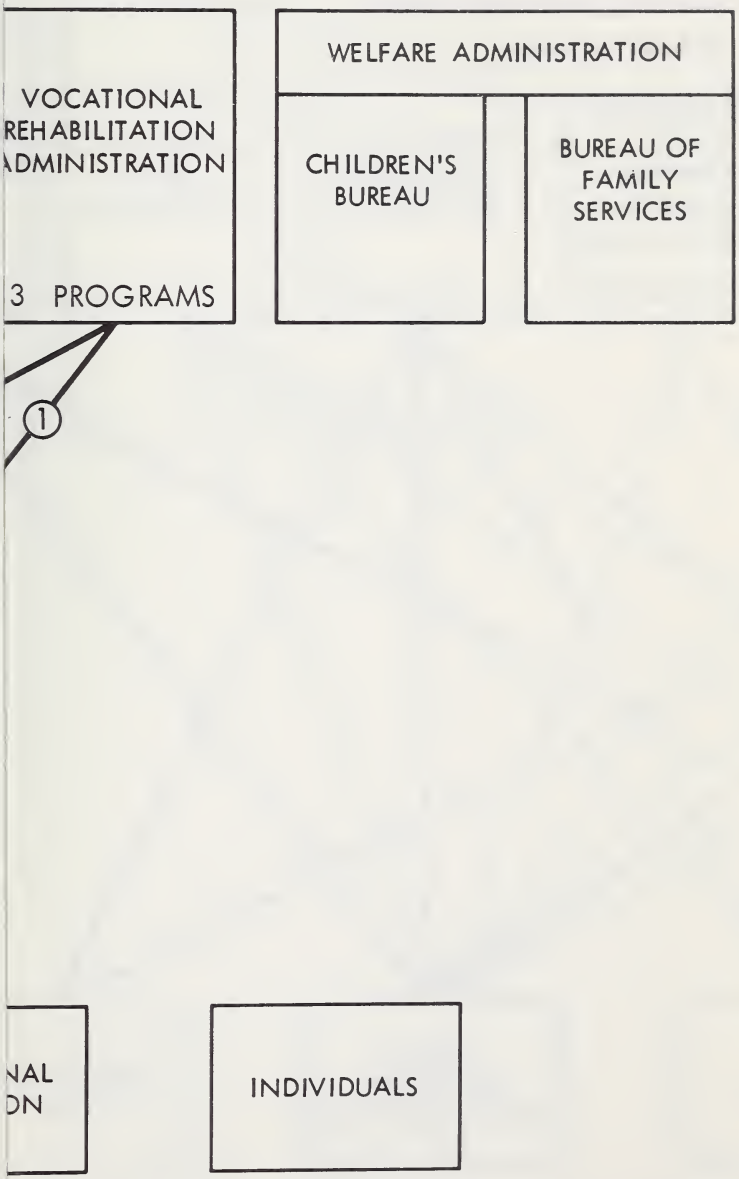
ELIGIBLE RECIPIENTS OF GRANTS AND CONTRACTS
— SERVICES (PROJECT) —



(2) NUMBER OF PROGRAMS FOR WHICH RECIPIENT IS ELIGIBLE



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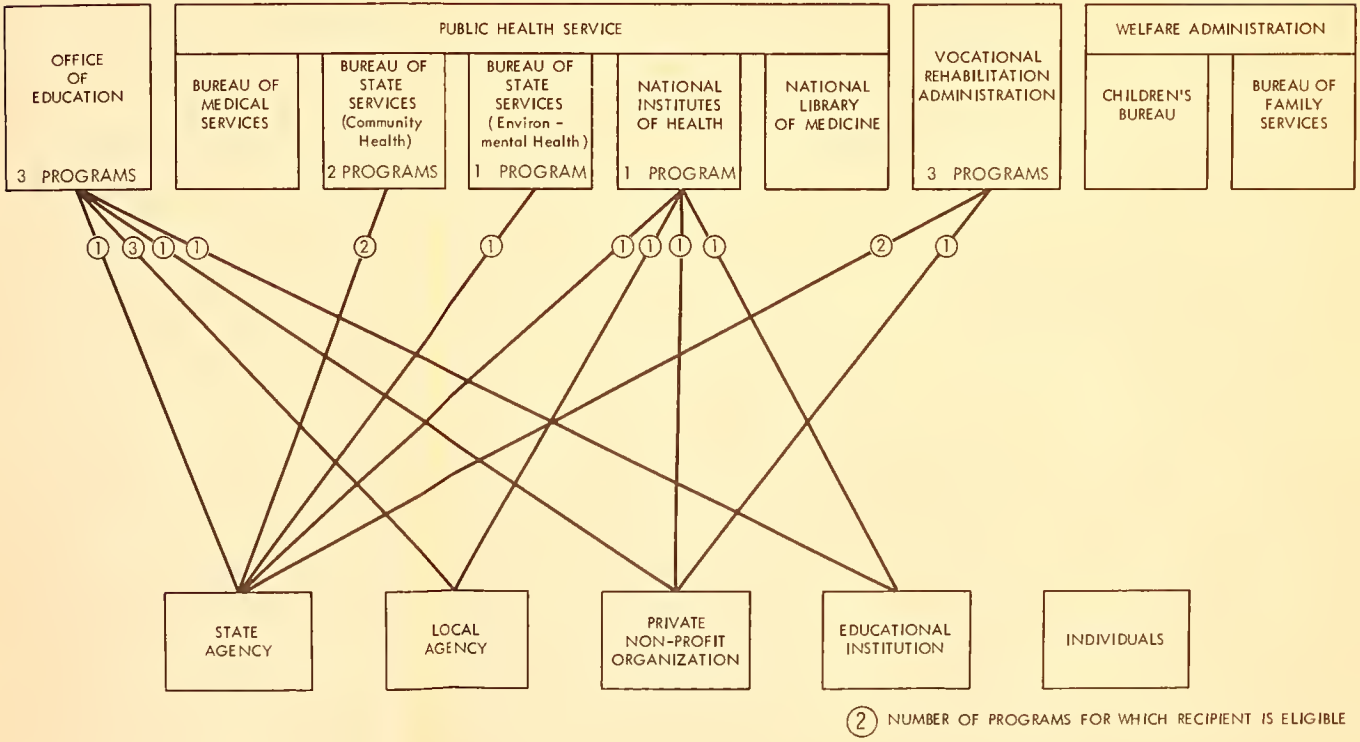


70-135 O - 66 (Face p. A68) No. 5



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

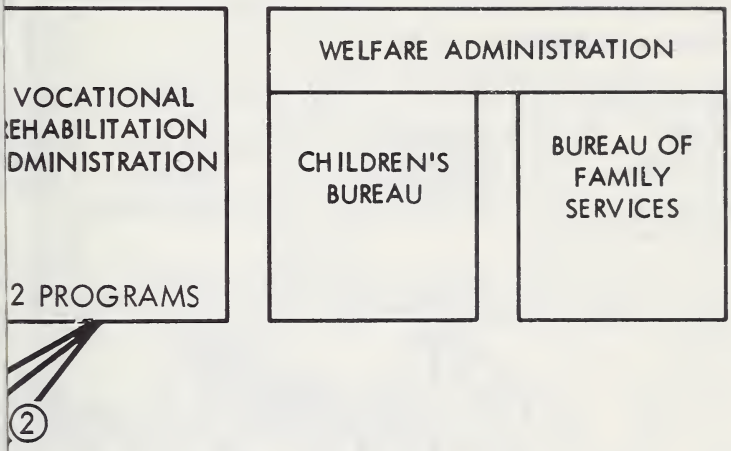
ELIGIBLE RECIPIENTS OF GRANTS AND CONTRACTS
— PLANNING —



70-135 O - 66 (Face p. A68) No. 5



D AWARDS



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N

INDIVIDUALS

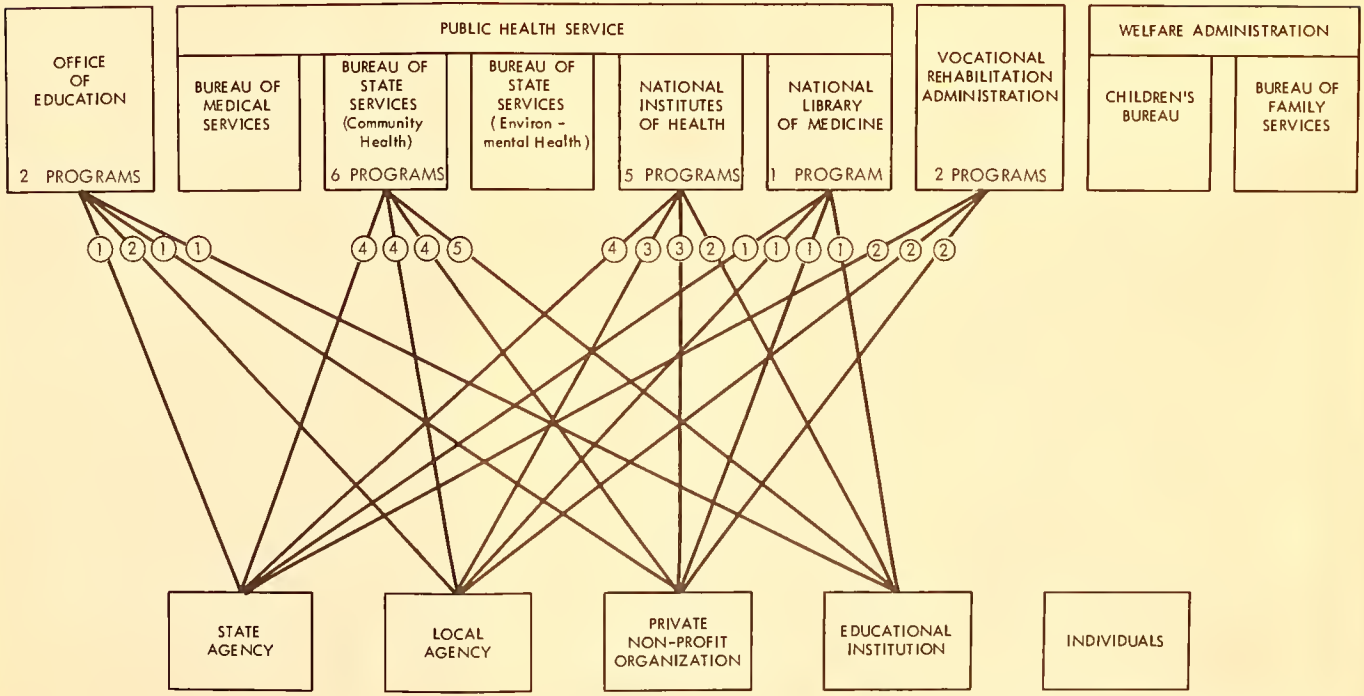
BER OF PROGRAMS FOR WHICH RECIPIENT IS ELIGIBLE

70-135 O - 66 (Face p. A68) No. 6



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ELIGIBLE RECIPIENTS OF GRANTS AND AWARDS
— CONSTRUCTION —





Research—Continued

	State	Local	PNP	Educ.	Indiv.
PUBLIC HEALTH SERVICE—continued					
National Library of Medicine:					
International grants and awards			X	X	X
Medical libraries research	X	X	X	X	X
Medical libraries resources	X	X	X	X	
Medical libraries special scientific projects	X	X	X	X	X
Total (4)	3	3	4	4	3
VOCATIONAL REHABILITATION ADMINISTRATION					
Research and demonstration	X	X	X	X	
Research and training centers	X	X	X	X	
Research fellowships					X
International rehabilitation (foreign governmental agencies and nonprofit organizations)					
Total (4)	2	2	2	2	1
WELFARE ADMINISTRATION					
Children's Bureau: Research grants	X	X	X	X	
Total (1)	1	1	1	1	
Bureau of Family Services (BFS pays 50 percent or more of State public welfare agency research costs)	X				
Total (1)	1				
OFFICE OF EDUCATION					
Vocational and technical education: Research, training, and development programs	X	X	X	X	
Total (1)	1	1	1	1	

Training

	State	Local	PNP	Educ.	Indiv.
PUBLIC HEALTH SERVICE					
Bureau of State Services (Community Health):					
Accident prevention:					
Fellowships					X
Training	X	X	X	X	
Cancer:					
Institutional training	X	X	X	X	
Cytotechnologist training	X	X	X	X	
Traineeships					X
Chronic diseases, training	X	X	X	X	
Community health:					
Fellowships					X
Training	X	X	X	X	
Dental health:					
Training				X	
Research training	X	X	X	X	
Educational improvements grants				X	
Health professions student loans				X	
International:					
PHS fellows					X
Training grants				X	
Mental retardation, training	X	X	X	X	X
Neutological and sensory diseases: Service training	X	X	X	X	X
Nursing:					
Fellowships					X
Professional traineeships					X
Nurse-scientist training				X	
Diploma schools				X	
Loans to students				X	X
Projects for improvement			X	X	
Public health:					
Graduate training				X	
Traineeships					X
Institutions				X	
Schools of public health				X	
Scholarship grants				X	
Total (27)	8	8	9	20	10

Training—Continued

	State	Local	PNP	Educ.	Indiv.
PUBLIC HEALTH SERVICE—continued					
Bureau of State Services (Environmental Health):					
Air pollution:					
Fellowships					X
Training	X	X	X	X	
Environmental health sciences: Research training			X	X	X
International:					
PHS fellows					X
Training grants				X	
Radiological health, training				X	
Solid waste disposal	X	X	X	X	
Total (7)	2	2	3	5	3
National Institutes of Health:					
Allergy:					
Fellowships					X
Research career program					X
Training	X	X	X	X	
Arthritis:					
Fellowships					X
Research career program					X
Training	X	X	X	X	
Cancer:					
Fellowships					X
Research career program					X
Training	X	X	X	X	
Cerebrovascular disease:					
Clinical traineeships					X
Training			X	X	
Child health and human development:					
Fellowships					X
Research career program					X
Training	X	X	X	X	
Dental health:					
Research training	X	X	X	X	
Fellowships					X
Research career program					X
General medical sciences:					
Fellowships					X
Research career program					X
Training	X	X	X	X	
Heart disease:					
Fellowships					X
Research career program					X
Training	X	X	X	X	
International centers for medical research and training				X	
International:					
Postdoctoral fellowships					X
PHS fellowships					X
Training grants				X	
Visiting program					X
Mental health:					
Fellowships					X
Research career programs					X
Training	X	X	X	X	
Neurological and sensory diseases:					
Direct traineeships					X
Fellowships					X
Research career program					X
Training	X	X	X	X	
Total (35)	9	9	10	12	23
National Library of Medicine:					
International:					
PHS fellows					X
Training grants					X
Medical libraries:					
Training	X	X	X	X	
Fellowships	X	X	X	X	X
Total (4)	2	2	2	2	3

Training—Continued

	State	Local	PNP	Educ.	Indiv.
VOCATIONAL REHABILITATION ADMINISTRATION					
Training and traineeships:					
Section 4 grants	X	X	X	X	
Section 7 grants	X	X	X	X	
Research fellowships					X
Traineeships					X
International rehabilitation (foreign governmental agencies and nonprofit organizations)					
Total (5)	2	2	2	2	2
WELFARE ADMINISTRATION					
Children's Bureau:					
Maternal and child health (project)	X			X	
Crippled children (project)	X			X	
Training grants	X			X	
Total (3)	3			3	
Bureau of Family Services (BFS provides 75 percent of State training costs for employees and persons preparing for employment)	X				
Total (1)	1				
OFFICE OF EDUCATION					
Vocational and technical: Education-research, training, and development programs	X	X	X	X	
Elementary and secondary education—Title V, State leadership	X				
Total (2)	2	1	1	1	

Services (formula)

	State	Local	PNP	Educ.	Indiv.
PUBLIC HEALTH SERVICE					
Bureau of State Services (Community Health):					
Cancer	X				
Chronic illness and aging	X				
Dental health	X				
General health	X				
Heart disease	X				
Home health services	X				
Tuberculosis	X				
Total (7)	7				
Bureau of State Services (Environmental Health): Radiological health	X				
Total (1)	1				
National Institutes of Health: Mental health	X				
Total (1)	1				
VOCATIONAL REHABILITATION ADMINISTRATION					
Basic support grants	X				
Provision of vocational rehabilitation services for social security beneficiaries	X				
Total (2)	2				
WELFARE ADMINISTRATION					
Children's Bureau:					
Maternal and child health service (formula)	X				
Crippled children (formula)	X				
Total (2)	2				
Bureau of Family Services:					
Old-age assistance	X				
Medical assistance for the aged	X				
Aid to families with dependent children	X				
Aid to blind	X				
Aid to permanently and totally disabled	X				
Aid to aged, blind, or disabled, or such aid and medical assistance for the aged	X				
Medical assistance program	X				
Total (7)	7				
OFFICE OF EDUCATION					
Vocational and technical education: State allotment programs	X				
Elementary and secondary education:					
Title I, educationally deprived children		X			
Title III, supplementary centers and services (operational)		X			
Title V, State leadership	X				
Total (4)	2	2			

Services (project)

	State	Local	PNP	Educ.	Indiv.
PUBLIC HEALTH SERVICE					
Bureau of State Services (Community Health):					
Cancer	X	X	X	X	
Community health services (chronically ill and aged)	X	X	X	X	X
Immunization	X	X			
Mental retardation	X	X	X	X	
Migrant health	X	X	X	X	
Nuerological and sensory diseases	X	X	X	X	
Tuberculosis control	X	X			
Venereal disease control	X	X			
Total (8)	8	8	5	5	1
Bureau of State Services (Environmental Health):					
Air pollution:					
Control	X	X			
Survey and demonstration	X	X	X		
Solid waste demonstration and investigation	X	X	X	X	
Total (3)	3	3	2	1	
Bureau of Medical Services: Hawaii leprosy project	X				
Total (1)	1				
National Institutes of Health:					
Community mental health, initial staffing	X	X	X		
Regional medical programs	X	X	X	X	
Total (2)	2	2	2	1	
National Library of Medicine:					
Publications	X	X	X	X	X
Special science projects	X	X	X	X	X
Regional libraries	X	X	X	X	
Resources	X	X	X	X	
Total (4)	4	4	4	4	2
VOCATIONAL REHABILITATION ADMINISTRATION					
Innovation grants	X				
Expansion grants	X	X	X		
Initial staffing grants	X	X	X		
Workshop improvement grants	X	X	X		
Grants for projects for training services	X	X	X		
Total (5)	5	4	4		
WELFARE ADMINISTRATION					
Children's Bureau:					
Maternal and child health (project)	X			X	
Crippled children (project)	X			X	
Maternity and infant care—Special project grants	X	X		X	
Health of school and preschool children—Special project grants	X	X			
Total (4)	4	2		3	
Bureau of Family Services: Repatriates	X				
Total (1)	1				
OFFICE OF EDUCATION					
Vocational and technical education—Residential school programs	X	X	X	X	
Total (1)	1	1	1	1	

Planning

	State	Local	PNP	Educ.	Indiv.
PUBLIC HEALTH SERVICE					
Bureau of State Services (Community Health):					
Areawide health facility	X				
Mental retardation, implementation	X				
Total (2)	2				
Bureau of State Services (Environmental Health): Solid waste disposal	X				
Total (1)	1				
National Institutes of Health: Regional medical programs	X	X	X	X	
Total (1)	1	1	1	1	
VOCATIONAL REHABILITATION ADMINISTRATION					
Statewide planning grants	X				
Project grants and assistance for workshops and rehabilitation facilities: State planning grants	X				
Correctional Rehabilitation Study Act grants			X		
Total (3)	2		1		
OFFICE OF EDUCATION					
Vocational and technical education: Residential school programs	X	X	X	X	
Elementary and Secondary Education:					
Title I, emotionally deprived children		X			
Title III, supplementary centers and services (planning)		X			
Total (3)	1	3	1	1	

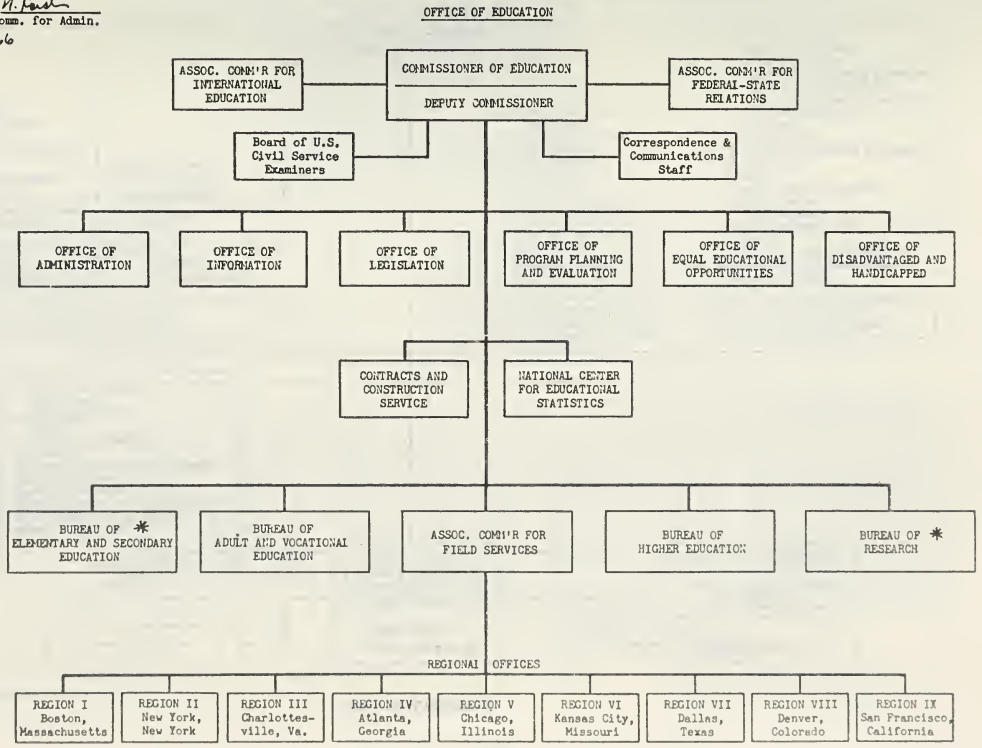
Construction

	State	Local	PNP	Educ.	Indiv.
PUBLIC HEALTH SERVICE					
Bureau of State Services (Community Health):					
Community mental health centers	X	X	X		
Health professions educational facilities				X	
Hospital and medical facilities	X	X	X	X	
Mental retardation, clinical facilities (university affiliated)	X	X	X	X	
Mental retardation, facilities	X	X	X	X	
Nursing				X	
Total (6)	4	4	4	5	
National Institutes of Health:					
Community mental health centers	X	X	X		
Health research facilities	X	X	X	X	
Mental health, hospital improvement	X				
National primate research centers (no applications accepted at this time)					
Mental retardation, research facilities	X	X	X	X	
Total (5)	4	3	3	2	
National Library of Medicine: Medical libraries	X	X	X	X	
Total (1)	1	1	1	1	
VOCATIONAL REHABILITATION ADMINISTRATION					
Project grants and assistance for workshops and rehabilitation facilities:					
Project development grants	X	X	X		
Construction grants	X	X	X		
Total (2)	2	2	2		
OFFICE OF EDUCATION					
Vocational and technical education: Residential school programs	X	X	X	X	
Elementary and secondary education: Title III, supplementary centers and services (operational)		X			
Total (2)	1	2	1	1	

Appendix E

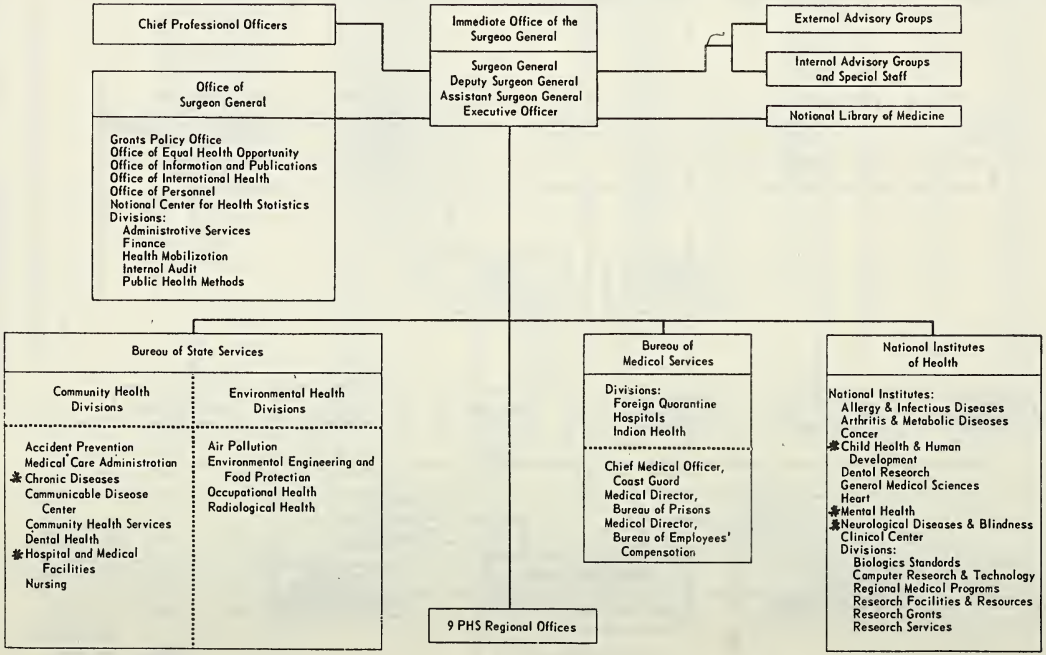
Mental Retardation Program; HEW Participating Units and Eligible Recipients

Approved: M. Foss
Asst. Comm. for Admin.
Date: 7/14/66



* MENTAL RETARDATION PROGRAM

PUBLIC HEALTH SERVICE



* MENTAL RETARDATION PROGRAM

February 15, 1966
PHS-OSG-MPS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Welfare Administration

WELFARE ADMINISTRATION

OFFICE OF THE COMMISSIONER

Responsible to the Secretary of Health, Education, and Welfare for directing the administration of the program of the Federal Government pertaining to assistance to persons in need and the provision of welfare assistance and services for children, the aging and other groups, and of maternal and child health services. Acts as the focal point in the Federal Government in the Welfare field. Provides leadership; develops program policies and objectives; oversees the planning and execution of programs; coordinates operations and activities; evaluates the effectiveness of operations and takes action to achieve improvements; and provides advice to and maintains relationships with Federal, State and International welfare and other professional agencies and organizations.
Staff officers advise and assist the Commissioner and Deputy Commissioner in civil defense planning, staff development, field liaison, legislative reference and public information matters. The Commissioner serves as Deputy Chairman of the President's Council on Aging.

DIVISION OF RESEARCH

Conducts and coordinates research studies concerned with the causes of dependency among poverty-prone groups and its prevention and reduction through family and special services, public assistance and other methods; evaluates the extent to which the current social welfare program, or any of its parts, meets its social objectives; administers programs of research and demonstration grants to public and non-profit agencies for projects relating to prevention and reduction of dependency, and improvement of existing programs.

MANAGEMENT OFFICE

Conducts and coordinates the financial, administrative, and personnel management activities of the Welfare Administration; performs management appraisal of Welfare Administration operations; coordinates formal work planning activities; serves as the contact point with the Office of the Secretary, Bureau of the Budget, Civil Service Commission, General Services Administration, General Accounting Office and appropriation committees of the Congress on financial, administrative and personnel management matters.

INTERNATIONAL OFFICE

Conducts and coordinates the international activities of the Welfare Administration; provides advisory service on U. S. foreign social policy; serves as contact point with U.S. and International welfare programs; develops programs for the technical training of foreign welfare personnel; recommends welfare experts for foreign assignments with AID and the U.N.; and conducts a program of cooperative research and demonstration projects in foreign countries with counterpart funds.

CUBAN REFUGEE PROGRAM STAFF

Administers the Cuban Refugee program which provides reception, registration, classification of skills, educational and emergency health services and welfare assistance and services to eligible refugees; works closely with other Federal, State, local and volunteer organizations in providing necessary services to refugees and in effecting their resettlement from Miami, Florida, to homes and jobs elsewhere in the country and overseas.

OFFICE OF AGING

Provides stimulation and guidance to States, local agencies and organizations in the field of aging; acts as a focal point for the coordination of all aging activities of the Department and serves as principal liaison with other Federal agencies; keeps abreast of emerging knowledge and trends and develops policies and programs related thereto; conducts research and compiles statistics in the field of aging; studies and evaluates State, community, and voluntary organization programs; encourages and assists in development of programs for training professional personnel; and publishes information related to needs and progress in training, research and aging in general.

BUREAU OF FAMILY SERVICES *

Administers Federal grants to States for old-age assistance and medical assistance for the aged, aid to families with dependent children, aid to the blind, and aid to the permanently and totally disabled; develops standards and provides consultation and assistance on improvement of State programs and provision of services directed to strengthening family life, self-support, self-care, and prevention of dependency; administers grants for demonstration projects in public welfare; carries responsibility for the Civil Defense Emergency Welfare Service program; the repatriation of American Nationals; participates in welfare planning for reception and assistance to refugees; and appraises the national public assistance programs and recommends improvements.

CHILDREN'S BUREAU *

Investigates and reports upon matters pertaining to the welfare of children and child life; formulates standards, guides, and recommendations for use in development of services for children and youth; provides advisory services to States and public and private agencies on development of programs for mothers and children; administers Federal grants to States for maternal and child health services, services for crippled children and child welfare services; administers grants for research, training and demonstration projects in child welfare; project grants for maternity and infant care and grants for research projects in maternal and child health and crippled children's services including services for mentally retarded children; provides technical assistance and makes surveys for State and local agencies responsible for programs for the control and treatment of juvenile delinquency; conducts training programs for foreign personnel; and conducts a program of international research in maternal and child health.

OFFICE OF JUVENILE DELINQUENCY AND YOUTH DEVELOPMENT

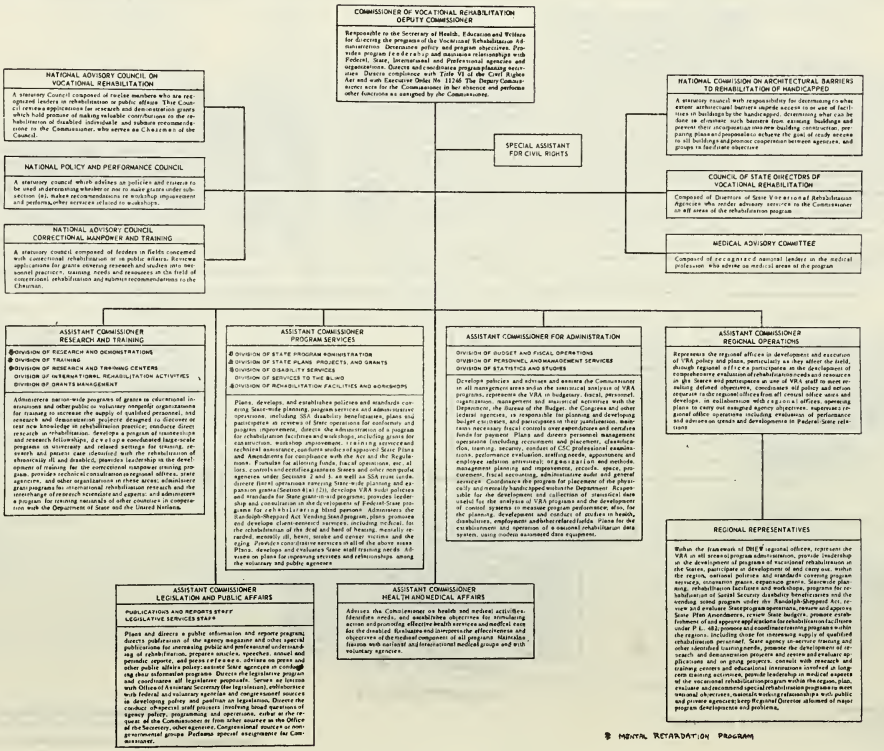
Administers Federal grants to public or non-profit organizations or institutions for support of demonstration projects and training programs in the field of Juvenile Delinquency and Youth Development; services the independent review panels that provide professional recommendations on grant applications; provides consultant services; works with the Division of Juvenile Delinquency Service of Children's Bureau which provides consultant services in correctional aspects of juvenile delinquency; is responsible for coordination of activities involving delinquency programs within the Department; and maintains a close working relationship with the staff of the President's Committee on Juvenile Delinquency and Youth Crime in developing the total Federal delinquency program.

REV 78-123 (7/27/64)

* MENTAL RETARDATION PROGRAM

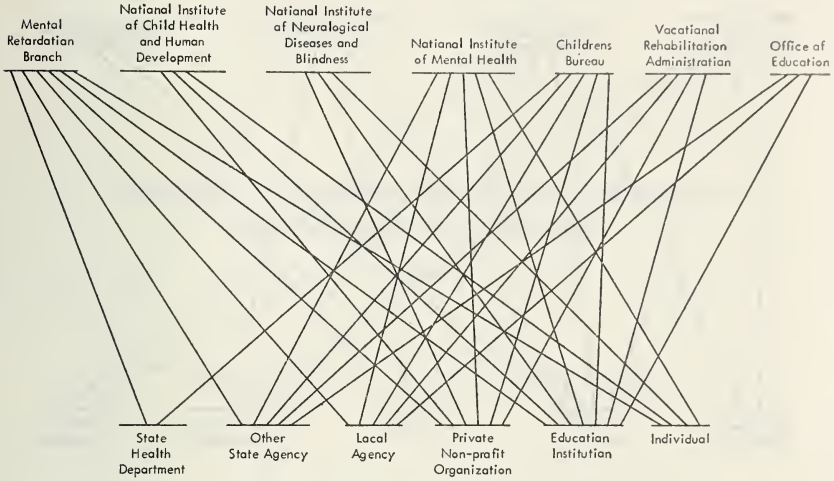
Organization — VOCATIONAL REHABILITATION ADMINISTRATION — Appendix A12-000

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
VOCATIONAL REHABILITATION ADMINISTRATION

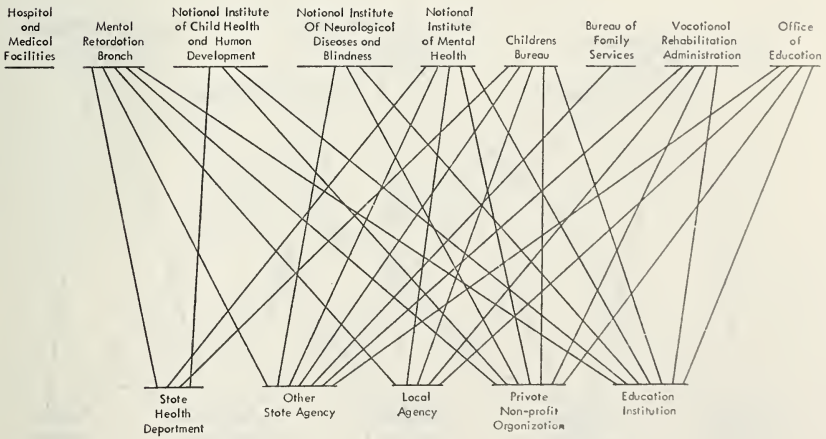


RECIPIENTS OF MENTAL RETARDATION TRAINING GRANTS

DHEW

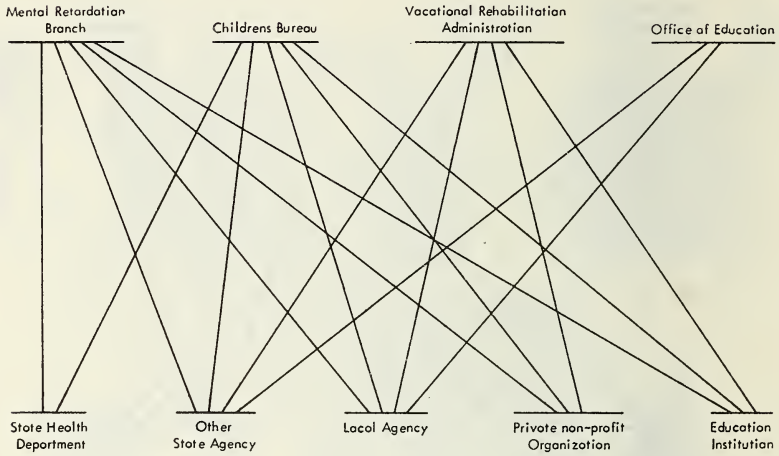


RECIPIENTS OF MENTAL RETARDATION RESEARCH AND DEMONSTRATION GRANTS



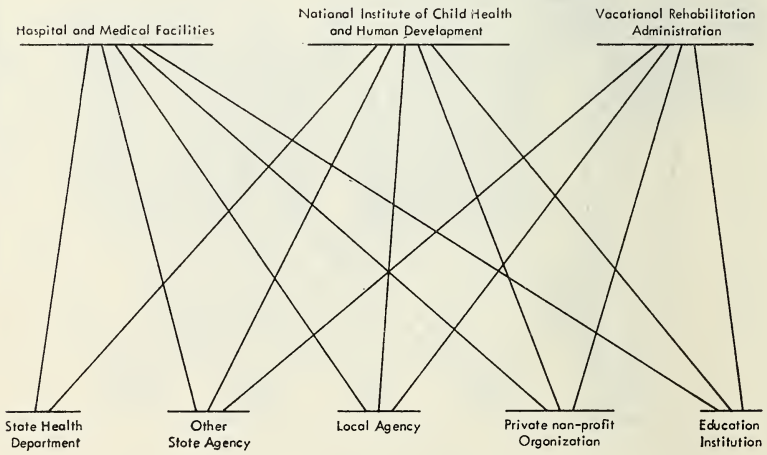
RECIPIENTS OF MENTAL RETARDATION SERVICE GRANTS

DHEW



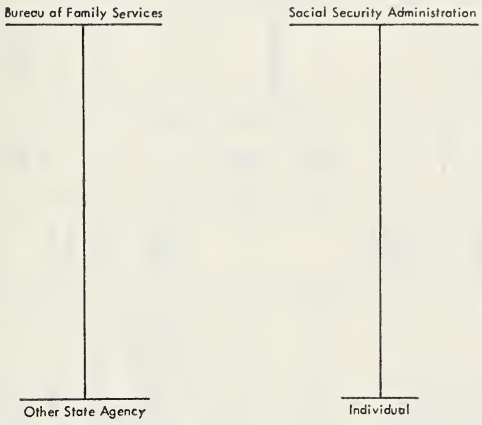
RECIPIENTS OF MENTAL RETARDATION CONSTRUCTION GRANTS

DHEW



RECIPIENTS OF INCOME MAINTENANCE PROGRAM FOR THE MENTALLY RETARDED

DHEW



Appendix F

HEW Health Programs: Legal Basis, Program Duration, Financing, and Congressional Review Committees

Program	Legal basis [1]	Duration of program [2] (years)	Final, fiscal year [3]	Fiscal year 1966 authorization [4]	Fiscal year 1966 appropriation [4]	Matched funds	Congressional committee [5]	
							House	Senate
Accident prevention:								
Research	Sec. 301, PHS Act	Cont.			$1,785,000	Cost sharing	A	A
Fellowships	do	Cont.			50,000	None	A	A
Training	do	Cont.			100,000	do	A	A
Air pollution:								
Research	Public Law 89-272	3	1967	$30,470,000	5,339,000	Cost sharing	A, C	A, D
Control grants	do	3	1967		5,000,000	Up to 2/3 for control agencies, and up to 3/4 for intermunicipal or interstate agencies.	A, C	A, D
Fellowships	do	3	1967		378,000	None	A, C	A, D
Training	do	3	1967		1,309,000	do	A, C	A, D
Survey and demonstration	do	3	1967		1,850,000	Up to 2/3 for control agencies, and up to 3/4 for intermunicipal or interstate agencies.	A, C	A, D
Allergy and infectious diseases:								
Research	Secs. 301(d) and 431, PHS Act	Cont.			43,466,000	Cost sharing	A	A
Gorgas Memorial	(45 Stat. 491), (62 Stat. 1213, 22 USC 278), (73 Stat. 573, Public Law 86-296).	Cont.			[6] 350,000	None	A	A
Fellowships	Secs. 301(c) and 433(a), PHS Act.	Cont.			1,071,000	do	A	A
Research career program award	do	Cont.			2,466,000	do	A	A
Training	Sec. 433(a), PHS Act	Cont.			9,059,000	do	A	A
Areawide health facility planning	Sec. 318, PHS Act	5	1969	5,000,000	5,000,000	Federal share not more than 50 percent.	A, C	A, C
Arthritis and metabolic diseases:								
Research	Secs. 301 and 431, PHS Act	Cont.			84,180,000	Cost sharing	A	A
Fellowships	Secs. 301(c) and 433(a), PHS Act	Cont.			2,905,000	None	A	A
Research career program award	do	Cont.			3,102,000	do	A	A
Training	Sec. 433(a), PHS Act	Cont.			14,206,000	do	A	A
Cancer:								
Formula grants	Public Law 89-156	Cont.			3,500,000	$1 State, $1 Federal	A	A
Project grants (including nonresearch training).	do	Cont.			13,933,000	None	A	A
Research	Sec. 301(d), PHS Act	Cont.			68,764,000	Cost sharing	A	A
Fellowships	Secs. 301(c) and 402(d), PHS Act	Cont.			1,825,000	None	A	A
Research career program award	do	Cont.			1,917,000	do	A	A
Training	Secs. 301(c) and 402(c), PHS Act	Cont.			10,900,000	do	A	A

Clinical traineeships (NHI)	Sec. 412(g), PHS Act	Cont.		(7)	(7)	do	A	A
Clinical traineeships (NINDB)	Secs. 431(a) and 433(a), PHS Act	Cont.			500,000	do	A	A
Training (NHI)	Sec. 412(g), PHS Act	Cont.		(7)	(7)	do	A	A
Training (NINDB)	Secs. 431(a) and 433(a) PHS Act	Cont.			600,000	do	A	A
Child health and human development:								
Research	Secs. 301 and 441, PHS Act	Cont.			38,081,000	Cost sharing	A	A
Fellowships	Secs. 301(c) and 444, PHS Act	Cont.			1,526,000	None	A	A
Research career program award	do	Cont.			2,181,000	do	A	A
Training	do	Cont.			7,937,000	do	A	A
Chronic diseases:								
Research	Sec. 301, PHS Act	Cont.			3,551,000	Cost sharing	A	A
Training	do	Cont.			200,000	None	A	A
Chronic illness and aged	Sec. 314(c), PHS Act	6	1967	(8)	12,300,000	$1 State, $1 Federal	A, C	A, C
Clinical cancer training (see Cancer training).								
Communicable diseases: Research	Sec. 301, PHS Act	Cont.			1,921,000	Cost sharing	A	A
Community health:								
Research	do	Cont.			3,816,000	do	A	A
Fellowships	do	Cont.			100,000	None	A	A
Training	do	Cont.			400,000	do	A	A
Community health services (chronically ill and aged.)	Sec. 316, PHS Act	6	1967	10,000,000	10,000,000	do	A, C	A, C
Community mental health centers:								
Construction	Public Law 88-164	3	1967	50,000,000	50,000,000	Variable based on State standards, Federal share not more than 2/3 or not less than 1/3.	A, C	A, C
Initial staffing	Public Law 88-105	3	1968 9	19,500,000	19,500,000	Federal share declines from 75 percent in 1st 15 months, to 60 percent in next 12 months, to 45 percent in next 12 months, to 30 percent in last 12 months.	A, C	A, C
Dental health:		6						
Formula	Sec. 314(c), PHS Act		1967	(8)	1,000,000	$1 State, $1 Federal	A, C	A, C
Research (BSS)	Sec. 301, PHS Act	Cont.			944,000	Cost sharing	A	A
Research (NIH)	Sec. 301(d), PHS Act	Cont.			11,008,000	do	A	A
Training (BSS) (auxiliary, utilization training).	Sec. 422(f), PHS Act	Cont.			2,399,000	None	A	A
Research training (NIH)	Secs. 301(d) and 422(f), PHS Act	Cont.			5,203,000	do	A	A
Research training (BSS)	Sec. 301, PHS Act	Cont.			150,000	do	A	A
Fellowships	Secs. 301(c) and 422(c), PHS Act	Cont.			668,000	do	A	A
Research career program award	do	Cont.			1,123,000	do	A	A
Educational improvement grants to schools of medicine, dentistry, osteopathy, optometry, and podiatry.	Public Law 89-290	4	1969	20,000,000	10,482,000	do	A, C	A, C

See footnotes at end of table, p. A91.

HEW Health Programs: Legal Basis, Program Duration, Financing, and Congressional Review Committees—Continued

Program	Legal basis [1]	Duration of program [2] (years)	Final, fiscal year [3]	Fiscal year 1966 authorization [4]	Fiscal year 1966 appropriation [4]	Matched funds	Congressional committee [5]	
							House	Senate
Environmental engineering and food protection: research.	Sec. 301, PHS Act	Cont.			$4,799,000	Cost sharing	A	A
Environmental health sciences:								
Research	do	Cont.			6,219,000	do	A	A
Research training	do	Cont.			3,578,000	None	A	A
General clinical research centers	Sec. 301(d), PHS Act	Cont.			28,500,000	do	A	A
General health	Sec. 314(c), PHS Act	6	1967	[6]	10,000,000	$1 State, $1 Federal	A, C	A, C
General medical sciences:								
Research	Sec. 301(d), PHS Act	Cont.			[10] 62,158,000	Cost sharing	A	A
Fellowships	Sec. 301(c), PHS Act	Cont.			10,948,000	None	A	A
Research career program award	do	Cont.			7,506,000	do	A	A
Training	Secs. 301(d) and 442, PHS Act	Cont.			41,375,000	do	A	A
General research support	Sec. 301(d), PHS Act	Cont.			45,200,000	do	A	A
Gorgas Memorial Laboratory (see Allergy and infectious diseases).								
Hawaii leprosy payment	Sec. 331, PHS Act	Cont.			1,200,000	None	A	A
Health professions educational facilities construction.	Public Law 88-581	6	1969	$75,000,000	75,000,000	Federal share not more than 66⅔ percent for new facilities, not more than 50 percent for others (except 75 percent for schools of public health).	A, C	A, C
Health professions student loan program.	Title VII, PHS Act, Public Law 89-290.	6	1969 [9]	15,400,000	15,400,000	Participating institutions required to deposit in loan funds no less than ⅛ of Federal contribution or no less than 1/10 of total loan fund.	A, C	A, C
Health research facilities	Title VII, PHS Act	13	1969	50,000,000	50,000,000	$1 institution, $1 Federal	A, C	A, C
Heart disease (see also Cerebrovascular disease):								
Control	Sec. 314(e), PHS Act	Cont.			9,500,000	$1 State, $1 Federal	A	A
Research	Sec. 301(d), PHS Act	Cont.			96,530,000	Cost sharing	A	A
Fellowships	Secs. 301(c) and 412(g), PHS Act.	Cont.			2,454,000	None	A	A
Research career program award	do	Cont.			3,921,000	do	A	A
Training	Secs. 301(d) and 412(g), PHS Act	Cont.			17,228,000	do	A	A

Home health services	Sec. 314(c), PHS Act	6	1967	[8]	9,000,000	$1 State, $10 Federal	A, C	A, C
Hospital and medical facilities construction (see also Areawide health facility planning).	Sec. 601, PHS Act	23	1969	260,000,000	258,500,000	Variable based on State standards, Federal share not more than ⅔ or not less than ⅓ (sec. 625(b), PHS Act).	A, C	A, C
Immunization project grants	Sec. 317, PHS Act	6	1968	11,000,000	8,000,000	None	A, C	A, C
International centers for medical research and training.	Secs. 301 and 308, PHS Act	Cont.			3,000,000	do	A	A
International grants and awards:								
International postdoctoral fellowships.	Secs. 301(c), 308, 433(a), PHS Act	Cont.			1,200,000	do	A	A
PHS fellows in foreign laboratories.	Secs. 301(c), 308, 402(d), 412(g), 422(c), 433(a), 444 of PHS Act; 103(b)(6) Clean Air Act; P.L. 89-291.	Cont.		[11]	[11]	do	A	A
Training grants, traineeships	Secs. 301(d), 303(a)(1), 402(c), 412(g), 422(f), 433(a), and 444, PHS Act.	Cont.		[11]	[11]	do	A	A
Visiting program	Secs. 207(f) and (g), PHS Act	Cont.		[11]	[11]	do	A	A
Research grants (foreign)	Secs. 301(d) and 308, PHS Act	Cont.		[11]	[11]	do	A	A
Research contracts (foreign)	Secs. 302(c), (2), (3), (5), (6), (7). (10), (11), (13), (14), and (15), Federal Property and Administrative Services Act of 1949, as amended; 27 F.R. 3017, Mar. 30, 1962.	Cont.		[12]	[12]	do	A	A
International medical research studies, translations—Foreign currency program.	Secs. 301 and 308, PHS Act	Cont.		[11]	[11]	do	A	A
Medical facilities construction, (see Hospital and medical facilities construction).								
Medical libraries:								
Research	Secs. 301 and 396, PHS Act	5	1970	3,000,000	945,000	do	A, C	A, C
Training	Secs. 301 and 394(a), PHS Act	5	1970	1,000,000	765,000	do	A, C	A, C
Fellowships	do	5	1970		20,000	do	A, C	A, C
Publications	Sec. 399, PHS Act	5	1970	1,000,000	200,000	do	A, C	A, C
Resources (in preparation)	Sec. 397, PHS Act	5	1970	3,000,000	2,000,000	do	A, C	A, C
Special scientific projects (in preparation).	Sec. 395, PHS Act	5	1970	500,000	100,000	do	A, C	A, C
Construction grants (in preparation).	Secs. 393 and 398, PHS Act	5	1970			In preparation	A, C	A, C
Establishment of regional medical libraries (in preparation).	Sec. 398, PHS Act	5	1970			do	A, C	A, C

See footnotes at end of table, p. A91.

HEW Health Programs: Legal Basis, Program Duration, Financing, and Congressional Review Committees—Continued

Program	Legal basis [1]	Duration of program [2] (years)	Final, fiscal year [3]	Fiscal year 1966 authorization [4]	Fiscal year 1966 appropriation [4]	Matched funds	Congressional committee [5]	
							House	Senate
Mental health:								
Formula grants	Sec. 314(c), PHS Act	6	1967	([6])	$6,750,000	$1 State, $1 Federal	A, C	A, C
Hospital improvement	Secs. 303(a) and (b), PHS Act	Cont.			18,000,000	None	A	A
Research	Secs. 301(d) and 303(a), (b), PHS Act.	Cont.			85,230,000	Cost sharing	A	A
Fellowships	Sec. 301(c), PHS Act	Cont.			4,961,000	None	A	A
Research career program award	do	Cont.			3,400,000	do	A	A
Training	Secs. 301(d) and 303(a)(1), PHS Act.	Cont.			86,231,000	do	A	A
Mental retardation:								
Implementation project grants	Public Law 89-97	2	[9] 1967	$2,750,000	2,750,000	$1 State, $3 Federal	A, C, D	A, B, C
Project grants	Public Law 89-156	Cont.			2,000,000	None	A	A
Project grants for training	do	Cont.			2,500,000	do	A	A
Mental retardation facilities construction:								
Research centers	Public Law 88-164	4	1967	6,000,000	6,000,000	Federal share not to exceed 75 percent of cost.	A, C	A, C
Clinical facilities (university affiliated).	do	4	1967	10,000,000	10,000,000	do	A, C	A, C
Facilities for mentally retarded	do	4	1968	12,500,000	12,500,000	Variable based on State standards, Federal share not more than ⅔ or not less than ⅓.	A, C	A, C
Migrant health	Sec. 310, PHS Act	3	1968	7,000,000	3,000,000	No fixed matching ratio	A, C	A, C
National Heart Institute graduate clinical training (see Heart disease).								
National primate research centers	Sec. 433(a), PHS Act, Public Law 87-395.	Cont.			7,000,000	None	A	A
Neurological and sensory diseases:								
Project	Public Law 89-156	Cont.			2,750,000	do	A	A
Service training	do	Cont.			1,275,000	do	A	A
Research	Secs. 301 and 431, PHS Act	Cont.			63,890,000	Cost sharing	A	A
Direct traineeships	Sec. 433(a), PHS Act	Cont.			2,200,000	None	A	A
Fellowships	Secs. 301(c) and 433(a), PHS Act.	Cont.			573,000	do	A	A
Research career program award	do	Cont.			2,580,000	do	A	A
Training	Sec. 433(a), PHS Act	Cont.			15,557,000	do	A	A
Nursing:								
Research	Sec. 301, PHS Act	Cont.			2,170,000	Cost sharing	A	A
Fellowships	do	Cont.			412,000	None	A	A
Professional traineeships	Sec. 821, PHS Act	5	1969	9,000,000	9,000,000	do	A, C	A, C
Nurse-scientist graduate training.	Sec. 301, PHS Act	Cont.			480,000	do	A	A
Diploma schools	Sec. 806, PHS Act	5	1969	7,000,000	2,500,000	do	A, C	A, C

Loans to students	Sec. 824, PHS Act	[9] 5	1969	8,900,000	8,900,000	Participating institutions required to deposit in loan funds no less less ⅛ of Federal contribution or no less than 1/10 of total loan fund.	A, C	A, C
Projects for improvement	Sec. 805, PHS Act	[9] 5	1969	3,000,000	3,000,000	None	A, C	A, C
Construction	Sec. 801, PHS Act	4	1969	15,000,000	15,000,000	Federal share not more than ⅔ or not less than ½.	A, C	A, C
Occupational Health: Research	Sec. 301, PHS Act	Cont.			2,705,000	Cost sharing	A	A
Public health:								
Graduate training	Sec. 309, PHS Act	9	1969	4,000,000	4,000,000	None	A, C	A, C
Traineeships	Sec. 306, PHS Act	13	1969	7,000,000	7,000,000	do	A, C	A, C
Schools of public health	Sec. 314(c), PHS Act	6	1967	[8]	3,500,000	do	A, C	A, C
Radiological health:								
Formula grants	do	6	1967	[8]	2,500,000	$1 State, $1 Federal	A, C	A, C
Research	Sec. 301, PHS Act	Cont.			2,546,000	Cost sharing	A	A
Training	Public Law 89-156	Cont.			2,500,000	None	A	A
Regional medical programs (heart disease, cancer, stroke).	Public Law 89-239	3	1968	50,000,000	[13] 25,000,000	Federal share not more than 90 percent of cost of construction or equipment.	A, C	A, C
Research contracts, NIH	Secs. 301(h), 302(c) (1), (2), (3), (5), (6), (7), (10), (11), (13), (14,) and (15), Federal Property and Administrative Services Act of 1949, as amended; 27 F.R. 3017, March 30, 1962; Public Law 89-115.	[14]		70,000,000	70,000,000	None	A	A
Scholarship grants to schools of medicine, dentistry, osteopathy, optometry, podiatry, or pharmacy.	Public Law 89-290	4	[9] 1969	[15]	200,000	do	A, C	A, C
Solid waste disposal:								
Demonstration studies and investigation grants.	Public Law 89-272	4	1969	7,000,000	2,000,000	Federal share not to exceed ⅔	A, C	A, D
Planning	do	4	1969		400,000	Federal share not to exceed ½	A, C	A, D
Research	do	4	1969		550,000	Cost sharing	A, C	A, D
Training	do	4	1969		150,000	None	A, C	A, D
Special research resources (see also National primate research centers).	Sec. 301, PHS Act	Cont.			12,150,000	do	A	A
Tuberculosis control:								
Formula grants	Sec. 314(b), PHS Act	Cont.			3,000,000	$1 State, $1 Federal	A	A
Project grants	Public Law 89-156	Cont.			9,700,000	None	A	A
Venereal disease control	Sec. 314(a), PHS Act, Public Law 89-156.	Cont.			6,229,000	do	A	A

See footnotes at end of table, p. A91.

Vocational Rehabilitation Administration

Program	Legal basis [1]	Duration of program [2] (years)	Final fiscal year [3]	Fiscal year 1966 authorization [4]	Fiscal year 1966 appropriation [4]	Matched funds	Congressional committee [5]	
							House	Senate
Basic support grants	Secs. 2 and 11, VR Act; Public Law 88-605; Public Law 89-156.	3	1968	$300,000,000	$160,500,000	See secs. 2 and 11, VR Act	A, B	A, C
Innovation grants (formula for projects within States).	Sec. 3, VR Act	3	1968	5,000,000	3,000,000	Federal share 90 percent for 1st 3 years of each project; 75 percent for 4th and 5th years.	A, B	A, C
Expansion grants	Sec. 4(a)(2)(A), VR Act	3	1968	(16)	3,000,000	Federal share not to exceed 90 percent.	A, B	A, C
Statewide planning grants (project)	Sec. 4(a)(2)(B), VR Act	3	1968	(16)	[9] 2,000,000	None	A, B	A, C
Provision of vocational rehabilitation service for social security beneficiaries paid for out of trust funds (general support).	Sec. 222, SS Act; Public Law 89-97.	Cont.		(17)	(18)	do	A	A
Project grants and assistance for workshops and rehabilitation facilities (State planning, project development, construction, and initial staffing).	Sec. 12, VR Act	5	1970 [19]	1,500,000	1,500,000	Federal share not to exceed 90 percent.	A, B	A, C
Workshop improvement grants (project).	Sec. 13(b), VR Act	5	1970 [19]	1,500,000	1,310,000	do	A, B	A, C
Grants for projects for training services.	do	5	1970 [19]	(20)	(20)	do	A, B	A, C
Research and demonstration	Sec. 4, VR Act	3	1968	(16)	20,570,000	Cost sharing	A, B	A, C
Research and training centers	do	3	1968	(16)	7,575,000	do	A, B	A, C
Training and traineeships	Secs. 4 and 7(a), VR Act	3	1968	(16)	24,800,000	Sec. 4 grants, cost sharing; inservice training grants, $9 Federal per $1 State; training and research fellowships, no matching funds.	A, B	A, C

International rehabilitation, research and training, foreign currency program.	Public Law 83-480, Public Law 85-477, Public Law 86-108, Public Law 86-341, and International Health Research Act of 1960.	Cont.			[9] 2,000,000	Cost sharing	A	A
Correctional Rehabilitation Study Act grants.	Sec. 16, VR Act	3	1968	500,000	500,000	do	A, B	A, C

See footnotes at end of table, p. A91.

Welfare Administration

Program	Legal basis [1]	Duration of program [2] (years)	Final fiscal year [3]	Fiscal year 1966 authorization [4]	Fiscal year 1966 appropriation [4]	Matched funds	Congressional committees [5]	
							House	Senate
Maternal and child health	Title V, pt. 1, SS Act	Cont.		$45,000,000	[21] $45,000,000	See sec. 502, SS Act	A, D	A, B
Crippled children	Title V, pt. 2, SS Act	Cont.		45,000,000	[22] 45,000,000	See sec. 512, SS Act	A, D	A, B
Maternity and infant care, special project grants.	Sec. 531, SS Act	5	1968	30,000,000	30,000,000	Federal share not to exceed 75 percent.	A, D	A, B
Health of school and preschool children, special project grants.	Sec. 532, SS Act	5	1970	15,000,000	15,000,000	do	A, D	A, B
Training grants	Sec. 516, SS Act	Cont.		([20])	([20])	Cost sharing	A, D	A, B
Research grants	Sec. 533, SS Act	Cont.		8,000,000	4,000,000	do	A, D	A, B
Old-age assistance	Title I, SS Act	Cont.			[23] 258,500,000	See title I, SS Act	A, D	A, B
Medical assistance for the aged	do	Cont.			[23] 350,100,000	do	A, D	A, B
Aid to families with dependent children.	Title IV, SS Act (Public Law 81-474).	Cont.			[23] 17,900,000	See title IV, SS Act	A, D	A, B
Aid to blind	Title X, SS Act (Public Law 81-474).	Cont.			[23] 2,500,000	See title X, SS Act	A, D	A, B
Aid to permanently and totally disabled.	Title XIV, SS Act	Cont.			[23] 41,000,000	See title XIV, SS Act	A, D	A, B
Aid to aged, blind, or disabled or such aid and medical assistance for the aged.	Title XVI, SS Act	Cont.		([24])	([24])	See title XVI, SS Act	A, D	A, B
Medical assistance programs	Title XIX, SS Act	Cont.			([18])	Sec title XIX, SS Act	A, D	A, B
Repatriates	Title XI, sec. 113, SS Act	Cont.			452,000	None	A, D	A, B

Program	Legal basis [1]	Duration of program (years) [2]	Final fiscal year [3]	Fiscal year 1966 authorization [4]	Fiscal year 1966 appropriation [4]	Matched funds	Congressional committee [5]	
							House	Senate
Vocational and technical education:								
State allotment programs [28]	Public Law 88-210	Cont.		$57,000,000	[26]	$1 Federal; $1 State	A	A
Research training, and development programs:								
Research	do	Cont.			[26]	Cost sharing	A	A
Training	Public Law 87-415	Cont.			[26]	do	A	A
Residential school programs	Public Law 88-210				[27]			
Elementary and secondary education:								
Title I—Educationally deprived children.	Public Law 89-10	3	1968	[26]	[26]	None	A, B	A, C
Title III—Supplementary centers and services (planning and operational).	do	5	1970	[26]	[26]	do	A, B	A, C
Title V—State leadership	do	5	1970	[26]	[26]	do	A, B	A, C

[1] Legal basis: PHS Act—Public Health Service Act, as amended; VR Act—Vocational Rehabilitation Act, as amended; SS Act—Social Security Act, as amended; F.R.—Federal Register.

[2] Number of years authorized for program, or continuous (subject only to annual review by Appropriations Committees).

[3] Final fiscal year of programs limited by statute.

[4] As of Apr. 15, 1966. Because of administrative adjustments, provisions of supplementary funds, and other changes, amounts indicated here may differ in some instances from those shown in 1966 edition of "Grants-in-Aid and Other Financial Assistance Programs Administered by the U.S. Department of Health, Education, and Welfare."

[5] Congressional committees concerned with periodic review of program:
House: A—Appropriations Committee; B—Education and Labor Committee; C—Interstate and Foreign Commerce Committee; D—Ways and Means Committee.
Senate: A—Appropriations Committee; B—Finance Committee; C—Labor and Public Welfare Committee; D—Public Works Committee.

[6] Included in $43,466,000 appropriation for allergy and infectious diseases research.

[7] See under Heart.

[8] Included in $50,000,000 total authorization for fiscal year 1966 under sec. 314(c), PHS Act, for following: Chronically ill and aged, dental health, general health, home health services, mental health, public health schools, radiological health.

[9] Includes carryover or continuation provisions. See "Legal basis" for details.

[10] Amount not appropriated directly, but allocated from appropriations to the several NIH Institutes.

[11] Not applicable.

[12] See Research contracts—NIH.

[13] Including $1,000,000 for administrative expenses.

[14] Continuous; contract authorization 1966–68, see sec. 301(h), PHS Act.

[15] No ceiling, but limitations on amounts of grants.

[16] Included in $80,000,000 total authorization for fiscal year 1966 under sec. 4, VR Act, for following: Expansion grants, statewide planning grants, research and demonstration, research and training centers, training and traineeships.

[17] No authorization limit, but ceiling specified in legal basis.

[18] Not available.

[19] 5-year program authorized, with maximum funding specified for only 3 years.

[20] Program begins in fiscal year 1967.

[21] Includes $4,750,000 earmarked for special projects for services for mentally retarded children.

[22] Includes $3,750,000 earmarked for special projects for crippled children who are mentally retarded.

[23] Vendor medical payments.

[24] Appropriations included in following Welfare Administration programs: Old Age Assistance, Medical Assistance for the Aged, Aid to Blind, Aid to Permanently and Totally Disabled.

[25] Including special program for practical nurse training (continuing program, no final fiscal year, fiscal year 1966 authorization, $5,000,000; fiscal year 1966 appropriation, $5,000,000; matching funds, $1 Federal to $1 State).

[26] Amount of health activities not identifiable.

[27] No appropriation for fiscal year 1966.

Appendix G

Research Activities—National Institutes of Health

Part I—Public Advisory Groups Authorized by Public Health Service Act as of October 1, 1965

Name	*Date established*
National Advisory Allergy and Infectious Diseases Council	1955
National Advisory Arthritis and Metabolic Diseases Council	1950
National Advisory Cancer Council	1937
National Advisory Child Health and Human Development Council	1963
National Advisory Dental Research Council	1948
National Advisory General Medical Services Council	1963
National Advisory Heart Council	1948
National Advisory Mental Health Council	1946
National Advisory Neurological Diseases and Blindness Council	1950
National Advisory Council on Health Research Facilities	1956
National Advisory Research Resources Committee	1962

Part 2—Study Sections and Other Grant-Review and Advisory Committees Established Administratively, Advisory to the National Institutes of Health as of October 1, 1965

Office of the Director:
- Cholera Advisory Committee.
- International Fellowship Review Committee.
- International Research Committee.

National Institute of Allergy and Infectious Diseases:
- National Institute of Allergy and Infectious Diseases Board of Scientific Counselors.
- Allergy and Infectious Diseases Training Grant Committee.
- Arboviruses Committee.
- Collaborative Research in Transplantation and Immunology Committee.
- Research Reagents Committee.
- Standardization of Allergens Committee.
- Vaccine Development Committee.
- Vaccine Development Committee; Rubella Vaccine Subcommittee.

National Institute of Arthritis and Metabolic Diseases:
- National Institute of Arthritis and Metabolic Diseases Board of Scientific Counselors.
- Arthritis and Metabolic Diseases Research Career Award Committee.
- Arthritis Training Grants Committee.
- Dermatology Training Grants Committee.
- Diabetes and Metabolism Training Grants Committee.
- Gastroenterology and Nutrition Training Grants Committee.
- Hematology Training Grants Committee.
- Orthopedics Training Committee.

National Cancer Institute: National Cancer Institute Board of Scientific Counselors.

National Institute of Child Health and Human Development:
- Aging Training Review Committee.
- Child Development and Mental Retardation Training Review Committee.
- Reproduction Training Review Committee.
- Special Program Planning Committee.

National Institute of Dental Research:
- National Institute of Dental Research Board of Scientific Counselors.
- Bio-Materials Research Advisory Committee.
- Dental Program-Project Committee.
- Dental Training Committee.

National Institute of General Medical Sciences:
- Anatomical Sciences Training Committee.
- Behavioral Sciences Training Committee.
- Biochemistry Training Committee.
- Biomedical Engineering Training Committee.
- Biophysical Sciences Training Committee.
- Clinical Research Training Committee.
- Epidemiology and Biometry Training Committee.
- General Medical Research Program-Project Committee.
- Genetics Training Committee.
- Medical Scientist Training Committee.
- Pharmacology and Toxicology Training Committee.
- Pharmacology/Toxiology Review Committee.
- Physiology Training Committee.
- Research Career Award Committee.

National Heart Institute:
- National Heart Institute Board of Scientific Counselors.
- Erythropoietin Committee.
- Heart Program-Project Committee.
- Heart Special Project Committee.
- Heart Training Committee.
- Thrombolytic Agents Committee.

National Institute of Mental Health:
- National Institute of Mental Health Board of Scientific Counselors.
- Behavioral Pharmacology Committee.
- Clinical Drug Evaluation Committee.
- Delinquency Grants Review Committee.
- Mental Health Program-Project Committee.
- Mental Health Project Grants in Special Areas Committee.
- Mental Health Project Grants to Community Programs Committee.
- Mental Health Project Grants to Hospitals Committee.
- Mental Health Research Career Award Committee.
- Mental Health Small Grant Committee.
- Mental Health Training Committee, Biological Sciences Subcommittee.
- Mental Health Training Committee, Inservice Training Subcommittee.
- Mental Health Training Committee, Nursing Subcommittee.
- Mental Health Training Committee, Pilot and Special Projects and Public Health Subcommittee.
- Mental Health Training Committee, Psychiatry Subcommittee.
- Mental Health Training Committee, Psychology Subcommittee.
- Mental Health Training Committee, Social Sciences Subcommittee.
- Mental Health Training Committee, Social Work Subcommittee.
- National Clearinghouse for Mental Health Information Advisory Committee.
- Pharmacology and Chemistry Committee.

National Institute of Neurological Diseases and Blindness:
- National Institute of Neurological Diseases and Blindness Board of Scientific Counselors.
- Communicative Disorder Research Training Committee.
- Evaluation of Clinical Therapy Advisory Committee.
- Neurological Science Research Training Committee, Section A.
- Neurology Program-Project Committee.
- Perinatal Research Committee.
- Vision Research Training Committee.

Division of Biologics Standards: Division of Biologics Standards Board of Scientific Counselors.

Division of Research Facilities and Resources:
- Animal Resources Advisory Committee.
- General Clinical Research Center Committee.
- General Research Support Advisory Committee.
- Health Research Facilities Scientific Review Committee.
- Primate Research Centers Advisory Committee.

Division of Research Grants:
Anatomy and Pathology Fellowships Review Committee.
Arthritis and Metabolic Diseases Program-Project Committee.
Behavioral Sciences A Fellowships Review Committee.
Behavioral Sciences B Fellowships Review Committee.
Biochemistry and Nutrition Fellowships Review Committee.
Biophysics and Biophysical Chemistry Fellowships Review Committee.
Cell Biology Fellowships Review Committee.
Child Health and Human Development Program-Project Committee.
Clinical Research Fellowships Review Committee.
Medicinal and Organic Chemistry Fellowships Review Committee.
Mental Health Fellowships Review Committee.
Microbiology Fellowships Review Committee.
Pharmacology and Endocrinology Fellowships Review Committee.
Physiology Fellowships Review Committee.
Psychological Sciences Fellowships Review Committee.
Accident Prevention Research Study Section.
Allergy and Immunology A Study Section.
Allergy and Immunology B Study Section.
Applied Physiology Study Section.
Bacteriology and Mycology A Study Section.
Bacteriology and Mycology B Study Section.
Behavioral Sciences Study Section.
Biochemistry Study Section.
Biophysics and Biophysical Chemistry Study Section.
Cardiovascular A Study Section.
Cardiovascular B Study Section.
Cell Biology Study Section.
Communicative Sciences Study Section.
Computer Research Study Section.
Dental Study Section.
Endocrinology Study Section.
Environmental Sciences and Engineering A Study Section.
Environmental Sciences and Engineering B Study Section.
Epidemiology and Disease Control Study Section.
Experimental Psychology A Study Section.
Experimental Psychology B Study Section.
General Medicine A Study Section.
General Medicine B Study Section.
Genetics Study Section.
Health Services Research Study Section.
Hematology Study Section.
History of The Life Sciences Study Section.
Human Embryology and Development Study Section.
Medicinal Chemistry A Study Section.
Medicinal Chemistry B Study Section.
Mental Health A Study Section.
Mental Health B Study Section.
Metabolism Study Section.
Neurology A Study Section.
Neurology B Study Section.
Nursing Research Study Section.
Nutrition Study Section.
Pathology A Study Section.
Pathology B Study Section.
Pharmacology and Experimental Therapeutics A Study Section.
Pharmacology and Experimental Therapeutics B Study Section.
Physiological Chemistry Study Section.
Physiology Study Section.
Psychopharmacology Study Section.
Radiation Study Section.
Surgery Study Section A.
Surgery Study Section B.
Toxicology Study Section.
Tropical Medicine and Parasitology Study Section.
Virology and Rickettsiology Study Section.
Visual Sciences Study Section.

Part 3—Summary of Review Actions on Competing Research Grant Applications Reviewed During Council Year 1965 With Start Dates in Fiscal Year 1965 [1]

INITIAL REVIEW GROUP (IRG)

[In thousands]

Action	National Institute of Allergy and Infectious Diseases		National Cancer Institute		National Heart Institute		National Institute of General Medical Services		National Institute of Mental Health	
	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved
Total reviewed	$17,159		$23,290		$34,306		$31,156		$53,296	
Approved applications:										
Amount equal to requested amount	9,317	$9,317	7,090	$7,090	11,259	$11,259	13,382	$13,382	17,070	$17,070
Amount less than requested amount	2,656	1,769	7,722	4,884	9,509	6,203	9,246	6,358	7,107	4,335
Amount greater than requested amount	122	143	430	527	211	230	241	285	931	1,211
Total approved by IRG	12,095	11,229	15,242	12,501	20,979	17,692	22,869	20,025	25,108	22,616
Priority score range:										
100 to 199	5,402	5,194	2,536	2,430	4,145	3,684	9,155	8,480	4,958	4,661
200 to 299	4,852	4,451	8,553	6,644	10,516	9,169	9,453	8,240	12,981	11,883
300 to 399	1,445	1,207	3,830	3,162	5,504	4,251	3,698	2,801	6,304	5,323
400 to 500	396	377	323	265	806	579	562	504	865	749
Other					8	9				
Disapproved applications	4,587		7,957		13,204		8,009		27,860	
All other IRG actions (deferred, etc.)	477		91		123		278		328	

See footnotes at end of table, p. A101.

Part 3—Summary of Review Actions on Competing Research Grant Applications Reviewed During Council Year 1965 With Start Dates in Fiscal Year 1965 [1]—Continued

ADVISORY COUNCIL

[In thousands]

Action	National Institute of Allergy and Infectious Diseases		National Cancer Institute		National Heart Institute		National Institute of General Medical Services		National Institute of Mental Health	
	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved
Total reviewed	$17,013		$23,271		$34,725		$30,860		$52,871	
Approved applications:										
Amount equal to IRG amount	10,651	$9,902	13,358	$11,106	19,644	$16,597	21,300	$18,884	24,078	$21,857
Amount less than IRG amount	354	115	441	310	468	402	227	208		
Amount greater than IRG amount	11	14	1,309	977	609	564	292	208	448	451
Disapproved by IRG	16	27	48	47	51	50			7	7
Other IRG action			41	51	25	17	53	56	16	16
No IRG review			8	8	425	425				
Total approved by Council	11,032	10,058	15,205	12,499	21,222	18,055	21,872	19,356	24,549	22,331
Priority score range:										
99 to 199	5,421	4,982	2,718	2,603	4,952	4,437	9,093	8,426	4,958	4,840
200 to 299	4,343	4,012	9,783	7,574	10,526	9,214	9,289	8,142	12,965	11,879
300 to 399	1,163	974	2,457	2,097	5,094	3,942	3,121	2,455	6,022	5,081
400 to 500	105	90	247	225	650	462	369	333	604	531
Other										
Disapproved applications:										
Approved by IRG	1,000		108		257		726		505	
Disapproved by IRG	4,522		7,827		13,148		7,847		27,494	
Other IRG action			5		22		34		42	
No IRG review							233			
Total disapproved by Council	5,522		7,940		13,427		8,840		28,041	
All other Council actions (deferred, etc.)	459		126		76		148		281	

INSTITUTE

	National Institute of Allergy and Infectious Diseases			National Cancer Institute			National Heart Institute		
	Amount requested	Amount awarded	Council amount	Amount requested	Amount awarded	Council amount	Amount requested	Amount awarded	Council amount
Awarded applications:									
Awarded amount equal to Council amount	$5,382	$4,973	$4,973	$9,773	$8,597	$8,597	$17,780	$15,437	$15,437
Awarded amount less than Council amount	2,777	2,313	2,602	4,172	2,649	2,865	2,834	1,639	2,170
Awarded amount greater than Council amount	205	182	166	989	849	781	217	146	116
Awarded, other Council actions									
Total direct costs awarded	8,364	7,468	7,741	14,934	12,095	12,243	20,831	17,222	17,723
Priority score range:									
99 to 199	5,198	4,663		2,718	2,596		4,863	4,255	
200 to 299	3,015	2,723		9,681	7,381		10,344	8,840	
300 to 399	151	82		2,337	1,941		5,000	3,692	
400 to 500				198	177		624	435	
Other									
Indirect costs awarded		1,106			1,661			2,336	
Council approved:									
Not awarded	1,973		1,721	138		138	242		201
Pending Institute action	29		29	49		49			

See footnotes at end of table, p. A101.

Part 3—Summary of Review Actions on Competing Research Grant Applications Reviewed During Council Year 1965 With Start Dates in Fiscal Year 1965 [1]—Continued

INSTITUTE

	National Institute of General Medical Services			National Institute of Mental Health		
	Amount requested	Amount awarded	Council amount	Amount requested	Amount awarded	Council amount
Awarded applications:						
Awarded amount equal to Council amount	$12,444	$11,347	$11,347	$18,333	$17,421	$17,421
Awarded amount less than Council amount	3,998	2,749	3,502	3,482	2,547	2,953
Awarded amount greater than Council amount	590	488	456	1,987	1,360	1,244
Awarded, other Council actions						
Total direct costs awarded	17,032	14,584	15,305	23,802	21,328	21,618
Priority score range:						
99 to 199	8,808	7,832		4,878	4,689	
200 to 299	6,562	5,488		12,777	11,506	
300 to 399	1,607	1,220		5,727	4,783	
400 to 500	54	44		420	350	
Other						
Indirect costs awarded		1,852			2,877	
Council approved:						
Not awarded	1,603		1,306	381		377
Pending Institute action	2,528		2,147			

INITIAL REVIEW GROUP (IRG)

Action	National Institute of Arthritis and Metabolic Diseases		National Institute of Child Health and Human Development		National Institute of Dental Research		National Institute of Neurological Diseases and Blindness		Division of Research Facilities and Resources		Office of International Research	
	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved
Total reviewed	$33,707		$20,892		$9,076		$25,279		$16,787		$1,818	
Approved applications:												
Amount equal to requested amount	14,326	$14,326	6,492	$6,492	2,939	$2,939	9,655	$9,655	3,561	$3,561	932	$932
Amount less than requested amount	9,206	6,309	4,698	2,843	1,859	967	6,135	4,476	6,478	3,872	871	841
Amount greater than requested amount	39	40	24	30	92	95	202	233			5	15
Total approved by IRG	23,571	20,675	11,215	9,365	4,890	4,001	15,991	14,363	10,038	7,432	1,808	1,788
Priority score range:												
100 to 199	6,430	6,180	2,064	2,001	1,305	1,303	4,694	4,494	4,218	3,615	1,785	1,766
200 to 299	10,882	9,635	6,008	4,981	1,714	1,497	7,769	7,023	3,924	2,613	23	22
300 to 399	5,585	4,349	2,824	2,153	1,798	1,127	3,270	2,662	1,881	1,189		
400 to 500	675	512	320	230	74	74	259	185	15	15		
Other												
Disapproved applications	9,903		9,643		3,848		8,973		6,749		10	
All other IRG actions (deferred, etc.)	232		34		338		315					

ADVISORY COUNCIL

Total reviewed	$33,498		$20,965		$9,068		$25,247		$16,787		$1,818	
Approved applications:												
Amount equal to IRG amount	21,964	$19,437	10,711	$8,972	4,692	$3,832	15,185	$13,713	9,637	$7,193	1,808	$1,788
Amount less than IRG amount	12	4	63	10			569	264	31	6		
Amount greater than IRG amount	49	51	79	79	53	53	73	79	356	356		
Disapproved by IRG	4	4			179	221	244	100				
Other IRG action	42	40	11	11			174	248				
No IRG review	14	14	13	13			148	147				
Total approved by Council	22,086	19,551	10,878	9,085	4,924	4,106	16,392	14,550	10,023	7,555	1,808	1,788
Priority score range:												
99 to 199	6,290	6,050	2,077	2,054	1,430	1,469	5,090	4,716	4,218	3,745	1,785	1,766
200 to 299	10,749	9,507	5,973	4,965	2,746	1,975	7,885	7,201	3,924	2,630	23	22
300 to 399	4,740	3,773	2,625	1,903	675	589	3,167	2,499	1,881	1,180		
400 to 500	306	221	203	164	74	74	249	134				
Other												

See footnotes at end of table, p. A101.

Part 3—Summary of Review Actions on Competing Research Grant Applications Reviewed During Council Year 1965 With Start Dates in Fiscal Year 1965 [1]—Continued

ADVISORY COUNCIL—Continued

Action	National Institute of Arthritis and Metabolic Diseases		National Institute of Child Health and Human Development		National Institute of Dental Research		National Institute of Neurological Diseases and Blindness		Division of Research Facilities and Resources		Office of International Research	
	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved	Amount requested	Amount approved
Disapproved applications:												
Approved by IRG	$1,309		$303		$146		$113		$15			
Dissapproved by IRG	9,833		9,643		3,669		8,542		6,331		$10	
Other IRG action			22				36					
No IRG review			69		10							
Total disapproved by Council	11,141		10,038		3,824		8,691		6,346		10	
All other Council actions (deferred, etc.)	271		49		320		164		418			

INSTITUTE

	National Institute of Arthritis and Metabolic Diseases			National Institute of Child Health and Human Development			National Institute of Dental Research		
	Amount requested	Amount awarded	Council amount	Amount requested	Amount awarded	Council amount	Amount requested	Amount awarded	Council amount
Awarded applications:									
Awarded amount equal to Council amount	$15,594	$14,621	$14,621	$8,208	$7,290	$7,290	$454	$291	$291
Awarded amount less than Council amount	3,112	2,042	2,472	1,758	1,074	1,181	3,132	1,586	2,557
Awarded amount greater than Council amount	1,373	965	918	710	472	431	84	84	76
Awarded, other Council actions									
Total direct costs awarded	20,079	17,628	18,011	10,676	8,836	8,902	3,670	1,961	2,924
Priority score range:									
99 to 199	6,047	5,728		2,077	2,054		1,370	905	
200 to 299	10,157	8,790		5,912	4,839		2,141	950	
300 to 399	3,835	3,073		2,524	1,805		160	106	
400 to 500	40	37		164	137				
Other									
Indirect costs awarded		2,480			1,398			251	
Council approved:									
Not awarded	895		701	114		98	618		578
Pending Institute action	23		20						

	National Institute of Neurological Diseases and Blindness			Division of Research Facilities and Resources			Office of International Research		
	Amount requested	Amount awarded	Council amount	Amount requested	Amount awarded	Council amount	Amount requested	Amount awarded	Council amount
Awarded applications:									
Awarded amount equal to Council amount	$10,885	$9,726	$9,726	$5,569	$3,956	$3,956	$1,805	$1,786	$1,786
Awarded amount less than Council amount	2,586	1,625	2,303	3,781	1,963	3,096			
Awarded amount greater than Council amount	399	343	289	673	633	503			
Awarded, other Council actions									
Total direct costs awarded	13,870	11,694	12,318	10,023	6,552	7,555	1,805	1,786	1,786
Priority score range:									
99 to 199	5,007	4,599		4,218	2,656		1,785	1,766	
200 to 299	6,810	5,756		3,924	2,717		20	20	
300 to 399	1,910	1,307		1,881	1,180				
400 to 500	142	32							
Other									
Indirect costs awarded		1,647			447			317	
Council approved:									
Not awarded	212		190						
Pending Institute action	406		351						

[1] Dollars shown are for direct costs only except when specified as indirect costs under Institute action.

NOTE.—Differences in the total number appearing in the 3 major groups (Initial Review Group, Advisory Council, and Institute) are due to applications being withdrawn by the requesting investigator at different points during the review process or due to applications receiving an Advisory Council review without receiving an initial review

Part 4—Summary of Review Actions on Competing Research Grant Applications Reviewed During Council Year 1965 With Start Dates in Fiscal Year 1965 [1]

[Number of applications]

Action	National Institute of Allergy and Infectious Diseases	National Cancer Institute	National Heart Institute	National Institute of General Medical Sciences	National Institute of Mental Health	National Institute of Arthritis and Metabolic Diseases	National Institute of Child Health and Humano Development	National Institute of Dental Research	National Institute of Neurological Diseases and Blindness	Division of Research Facilities and Resources	Office of International Research
INITIAL REVIEW GROUP (IRG)											
Total reviewed	749	753	1,164	1,117	1,736	1,367	697	246	868	65	46
Approved applications:											
Amount equal to requested amount	416	296	497	573	705	681	289	111	402	18	38
Amount less than requested amount	91	127	231	206	138	256	113	32	155	23	4
Amount greater than requested amount	6	14	7	10	32	1	2	2	8	----	2
Total approved by IRG	513	437	735	789	875	938	404	145	565	41	44
Priority score range:											
100 to 199	193	72	109	231	149	219	63	29	146	17	35
200 to 299	223	233	360	364	399	443	212	68	267	19	9
300 to 399	75	117	228	162	279	247	113	45	139	4	----
400 to 500	22	15	37	32	48	29	16	3	13	1	----
Other	----	----	1	----	----	----	----	----	----	----	----
Disapproved applications	230	311	425	321	850	424	291	98	295	24	2
All other IRG actions (deferred, etc.)	6	5	4	7	11	5	2	3	8	----	----
ADVISORY COUNCIL											
Total reviewed	739	753	1,169	1,091	1,726	1,358	699	246	872	65	46
Approved applications:											
Amount equal to IRG	460	403	705	739	844	893	383	136	540	37	44
Amount less than IRG amount	3	14	8	3	----	1	1	----	18	1	----
Amount greater than IRG amount	1	14	9	5	4	3	2	3	2	2	----
Disapproved by IRG	1	2	1	----	1	1	----	2	10	----	----
Other IRG action	----	2	1	2	1	1	1	----	3	----	----
No IRG review	----	2	6	----	----	1	1	----	9	----	----
Total approved by Council	465	437	730	749	850	900	388	141	582	40	44

Priority score range:											
99 to 199	193	79	121	225	149	220	64	30	165	17	35
200 to 299	204	234	364	353	397	438	210	74	270	19	9
300 to 399	62	111	215	152	268	227	102	34	135	4	
400 to 500	6	13	30	19	36	15	12	3	12		
Other											
Disapproved applications:											
Approved by IRG	43	4	13	23	21	32	15	6	3	1	
Disapproved by IRG	226	306	423	313	842	420	291	96	280	23	2
Other IRG action		1	2	1	1		1		1		
No IRG review				1			2	1			
Total disapproved by Council	269	311	438	338	864	452	309	103	284	24	2
All other Council actions (deferred, etc.)	5	5	1	4	12	6	2	2	6	1	
INSTITUTE											
Awarded applications:											
Awarded amount equal to Council amount	230	348	633	443	664	686	323	20	415	29	43
Awarded amount less than Council amount	96	53	69	75	91	91	33	65	58	7	
Awarded amount greater than Council amount	5	19	7	13	42	34	19	3	16	4	
Awarded, other Council actions											
Total direct costs awarded	331	420	709	531	797	811	375	88	489	40	43
Priority score range:											
99 to 199	184	79	117	217	144	213	64	28	162	17	35
200 to 299	140	228	355	239	388	411	206	53	238	19	8
300 to 399	7	102	208	73	248	184	96	7	82	4	
400 to 500		11	29	2	17	3	9		7		
Other											
Indirect costs awarded											
Council approved:											
Not awarded	103	8	11	81	39	43	7	31	13		
Pending Institute action	1	3		105		1			9		

[1] Excludes applications with requested start dates in fiscal year 1965 which were actually awarded during fiscal year 1966 from fiscal year 1966 funds.

NOTE.—Differences in the total number appearing in the 3 major groups (Initial Review Group, Advisory Council, and Institute) are due to applications being withdrawn by the requesting investigator at different points during the review process or due to applications receiving an Advisory Council review without receiving an initial review.

Part 5—Summary of Planning Mechanisms and Procedures

JUNE 9, 1966.

Hon. JOHN H. GARDNER,
Secretary, Department of Health, Education, and Welfare,
Washington, D.C.

DEAR MR. SECRETARY: In the course of your testimony before this Subcommittee on May 27, 1966, we requested that certain information be supplied to the Subcommittee regarding the efforts being made by the NIH to strengthen its planning mechanisms and procedures, both in regard to overall NIH planning and also internal planning by the individual Institutes. I am writing at this time to clarify the information desired.

The Wooldridge Committee stated that "the most important *organizational* need of NIH is the strengthening of its capacity for long-range planning, for determining the optimum utilization of its funds, and for ensuring that its activities and policies have the continued understanding and approval of the scientific and lay public." To help accomplish this strengthening, the Committee recommended the establishment of a Policy and Planning Council, composed of prominent non-government scientists and laymen, to provide a high level advisory service to the Director of NIH in the making of major plans and policies, especially those related to the allocation of NIH funds and resources. The Committee also made a recommendation: "To support the decision-making activities of the Director and the Council, NIH will need a strong and analytical planning staff. Under the guidance of the Director this staff should concentrate its attention on the generation and continual updating of a master plan covering all major aspects of the activities contemplated during the several succeeding years, together with the analysis and judgments supporting it."

It would be appreciated if you would supply information as to what measures (a) have been taken and (b) presently are planned by the Department to implement these two Wooldridge Committee recommendations, with respect to both the intramural and extramural NIH programs, and also (c) what additional measures, if any, the Department believes may be necessary or desirable to further augment NIH's planning capabilities.

In Dr. Shannon's initial commentary on the Wooldridge Committee report it was stated that in order to implement the recommendations pertaining to planning, proposals had been made to abolish the existing Office of Program Planning, establish a new position of Associate Director for Planning and reorganize the planning and analytical functions into a new, more sophisticated and professionally capable framework.

It would be appreciated if you would advise us as to:

(a) The functions and responsibilities of the Office of Program Planning, including its composition.

(b) The in-house Committee or body primarily responsible for the planning functions of each of the individual Institutes and Divisions, including the composition thereof and any positions currently vacant.

(c) What programing and planning functions are performed by the Committees or groups identified in paragraph (b).

(d) What major programs are being implemented as a result of such Institute or Division action.

(e) Which Advisory Councils for the nine Institutes and four divisions of NIH have established Subcommittees for planning or have similar means by which they assist in planning.

(f) The frequency and length of time of the meetings of such Subcommittees and the format used in presenting their recommendations for new programs to the Council and in turn to the Institute.

(g) What major recommendations have been made and programs inaugurated within the past few years as a result of such planning efforts.

As this Subcommittee is in process of completing its work, it would be appreciated if this information could be furnished as soon as possible.

Again, I wish to thank you and your associates for appearing before the Subcommittee last week.

Sincerely yours,

PAUL G. ROGERS,
Chairman, Special Subcommittee on HEW Investigation.

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, June 29, 1966.

Hon. PAUL G. ROGERS,
Chairman, Special Subcommittee on HEW Investigation, House Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. ROGERS: In your letter of June 9, 1966, you asked for further information concerning the planning mechanisms and procedures of the National Institutes of Health as an extension of our discussion of these matters during my testimony before your committee on May 27, 1966. I should like to respond to your request by commenting in this letter upon the status of the follow-through on the Wooldridge Committee recommendations relating to planning, and attaching a statement which provides detailed information relating to items (a) through (g) set forth in the second page of your June 9 letter.

THE POLICY AND PLANNING COUNCIL

You ask first about the status of the Wooldridge Committee recommendation on the establishment of a "Policy and Planning Council" advisory to the Director of the National Institutes of Health. As noted in the NIH commentary on the Wooldridge Committee Report, the specific concept of the role and function of this group as advanced by the Wooldridge Committee would require drastic modifications of existing operating relationships *vis a vis* the existing advisory council structure. The NIH advanced the views that the essential objective sought in this recommendation could be achieved in a less disruptive manner by the creation of an Advisory Committee to the Director of the National Institutes of Health. The function of this group would be to assist the Director in the processes of policy formulation, program development, and evaluation, and examining the implications of broad economic, scientific and public policy considerations for the direction, emphasis and character of NIH activity. After discussions of this matter with the Surgeon General, the Office of the Secretary concurred in this approach and directed the establishment of such an advisory committee. Thus an Advisory Committee to the Director of the National Institutes of Health has been formally initiated. It will be comprised of twelve outstanding individuals drawn from relevant fields of science, medicine, academic and public affairs. Invitations have been extended to individuals selected to comprise the initial membership of the group. The committee will be fully operative in fiscal year 1967 and will meet a minimum of four times each year in Bethesda, Maryland. A secretariat staff for the committee is being set up within the Office of Program Planning in the Office of the Director of NIH.

STRENGTHENING THE PLANNING FUNCTION AT NIH

While the recommendations of the Wooldridge Committee relating to strengthening the planning and analytical functions at the National Institutes of Health have had full concurrence at all levels in the Department, the connotations associated with the concept of a "master plan" which the committee advanced has required more careful examination. This reservation is engendered by the fact that the biological and medical sciences, and the structure of institutions and scientists in which they are based, are not yet at a stage of development that will permit any major degree of central direction. The base of knowledge and the scientific concepts in the biomedical area are yet so empirical, the choice amongst alternative courses of action so fraught with uncertainties, and the significant scientific leads still so dependent upon random intuition and inspiration that dependence upon guiding programs through any elaborate master plan may stifle rather than stimulate progress.

However, there is clear agreement that intelligent formulation of policy and direction of national programs for medical research does require the critical examination of the growing competition for resources, the scientific and technical potential for the pursuit of specific objectives, the long-term economic and social consequences of medical research expenditures, and the influence exerted upon the course of science and medicine and its relevant institutions. In this context the National Institutes of Health has moved to strengthen its arrangements and staffs for planning analysis. The actions taken include:

(a) Additions to the staff of the Office of Program Planning to expand and improve the study and analytical capabilities of that office in support of the decision-making activities of the Director of the National Institutes of Health. These staff additions, together with supporting personnel, have brought the staff of the Office of Program Planning from a level of thirty-

five employees at the beginning of fiscal year 1966 to a total of fifty-five employees currently on duty. Present budget plans provide for a total of sixty-four positions for this function in fiscal year 1967. Particular emphasis has been given in this expansion to the appointment of individuals with background and experience in operations research, manpower studies, and analysis of operating data to provide an adequate basis for cost benefit and related analytical procedures.

(b) An expanded program of both staff and contract studies has been developed as a means of providing broad, in-depth inquiry into the factors bearing upon the development of NIH programs and the longer range considerations which will govern the further advancement of medical research. These efforts have encompassed a wide range of specific inquiries, including studies of the characteristics and dynamics of medical research manpower, trends in graduate education in the medical sciences, the economics of medical research, the faculty requirements for new medical schools, and the sources of funds for medical research. These endeavors have been a part of the broad plan of contract studies. Staff inquiries have been made into the character of NIH collaborative activities, the source and characteristics of advisory council memberships, the relationship of NIH and National Science Foundation programs, the legislative requirements relating to the care and treatment of laboratory animals, the nature of new program development planned by NIH Institutes and Divisions, and to the problem areas in support of the program direction process.

(c) The strengthening of the analytical and planning capability of the several Institutes and Divisions of the National Institutes of Health and providing for a stronger and more effective role for advisory councils in the process of program development and evaluation. These efforts are reported upon in detail in the enclosed statement.

Efforts along these lines will be continued in the forthcoming fiscal year and it is anticipated that by the end of fiscal year 1967 a major improvement in the entire planning, analytical and program development framework for the National Institutes of Health will have been accomplished.

FURTHER DEPARTMENTAL ACTION

The changes noted above are taking place in a setting which involves a major overhauling of the framework of the entire Department of Health, Education, and Welfare for planning, program development and related analytical functions. The creation of the position of Assistant Secretary for Program Coordination and the action being taken under the direction of Mr. William Gorham, the incumbent of this position, to introduce a planning, programming and budgeting system for Departmental programs will, I believe, engender stronger and more effective planning and decision-making arrangements within all departmental components. Under this system particular attention will be given to the special problems of sound decision-making in research programs such as those of the National Institutes of Health.

I hope that the above comments, supplemented by the responses contained in the attached statement, will provide the clarification that you have sought. I shall be pleased to provide further information if you should find it necessary.

With best wishes.

Sincerely,

JOHN W. GARDNER, *Secretary.*

PLANNING AND PROGRAMMING ARRANGEMENTS AT THE NIH

(Response to the specific inquiries contained in Congressman Rogers' letter to the Secretary, June 9, 1966)

Comment is provided in the order of the questions as set forth in the June 9 letter.

Question: (a) Functions and responsibilities of the Office of Program Planning.

Response: The Office of Program Planning is a staff organization within the Office of the Director of the NIH which performs reporting, analytical and planning functions in support of the program development, policy formulation and executive functions of the Office of the Director. Its composition and functions are as follows:

Office of the Chief

Plans, develops, and directs all the activities of the Office of Program Planning; participates directly on a day-to-day basis with the Director of NIH and his immediate staff, and on a less continuing basis with Institute Directors in development of NIH policies and programs; in particular, provides the analyses and assessments which provide the basis for policy and program determinations; provides leadership and guidance in developing and strengthening the framework for planning and program analysis activities at the Institute and Division levels.

Resources analysis staff

Studying and evaluating the external factors, trends and influences important to or affecting NIH activities and the status and projections of medical research and training, its resources and requirements generally, including research manpower, expenditures, facilities, and the ambient economic, social and institutional factors bearing upon such resources.

Program analysis staff

Conducts a program for the analysis and interpretation of operating data relating to NIH activities, programs and policies in specific reference to current problems, issues and general process of planning program development and policy formulation. Conducts program analysis studies relating the status and character of activities with program objectives and budgetary plans, provides for the effective management of scientific and technical information and for the effective operation of the NIH framework for scientific communication.

Legislative analysis staff

Assessing the need for and proposing the character of changes in the statutory base of NIH activities in the light of analytical and planning factors, and the development of specifications for legislative language. Analyzing legislative developments of general or special interest to NIH, preparation of reports, position papers and other statements on pending legislation and legislative proposals, coordinating and providing advice to the Institutes and Divisions on legislative matters, and providing a central point for servicing the legislative material needs of NIH.

Special projects staff

Conducting special studies, developing special reports and staff documents, analyzing emergent problems and carrying out special assignments relating to any phase of NIH activities as requested, for internal staff purposes, for other government agencies and the Congress.

Question: "(b) The in-house Committee or body primarily responsible for the planning functions of each of the individual Institutes and Divisions, including the composition thereof and any positions currently vacant."

Responses:

(1) *National Cancer Institute* (NCI). Program planning is not accomplished by any single committee or group which has the responsibility for overall planning. Rather, planning is achieved by the integration and synthesis of the activities of three operational levels: the planning functions performed by the major program leaders and their senior staffs; the review and assessment of the plans of each major research area by the Scientific Directorate from the perspective of the total NCI program; and the functions of the Office of the Associate Director for Program, within the Office of the Director, which provides the program leaders with competence in systematic planning approaches and techniques, and serves as the focal point for synthesizing various program plans and efforts into overall program documents which are used for various purposes: budget preparation, projected planning, presentation to the Council, and others.

The Scientific Directorate is the senior staff group of the Institute responsible for advising the Director on major program issues, policies, and planning requirements. Its members include: Scientific Director for Chemotherapy, as Chairman; Scientific Director for Etiology, as Vice-Chairman; Associate Director for Program, as Executive Secretary; Clinical Director; Executive Officer; Scientific Director for General Laboratories and Clinics; Associate Director for Extramural Activities; Associate Scientific Director for Viral Oncology; Chief, Medicine Branch; Chief, Cancer Chemotherapy National Service Center; Chief, Laboratory of Chemical Pharmacology; Chief, Biometry Branch; Special Assistant to the Associate Director for Extramural Activities; and (as nonvoting members) Chief, Grants and Research Contracts Operations Branch; and Chief, Research Information Branch. There are no vacancies.

The Office of the Associate Director for Program currently includes the Program Planning Officer and the Scientific and Technical Information Officer and their staffs. Since program planning is accomplished as a joint effort with the program leader and senior scientists, in the respective program area in which the planning is being accomplished, it has not been necessary, to date, to expand the planning staff in the Office of the Director beyond its present capacity. However, as the demands on this staff increase, additional individuals with planning competence will be recruited.

(2) *National Heart Institute* (NHI). The position of Associate Director for Planning is identified organizationally but at present is vacant. The recently appointed Director of NHI is now giving major attention to recruiting, staffing, definition of organizational responsibilities of this post, and to recruiting appropriate staff. Meanwhile, the senior administrative staff of NHI (Associate Director, Extramural Branch; Director, Intramural Research; Associate Director, Collaborative Studies; and Executive Officer of NHI—added to by senior staff of the Blood Program Branch and Artificial Heart Branch) meet once weekly in a planning capacity.

It is intended that the Office of Planning shall include the already established Information Office and the Reports and Analysis Branch.

(3) *National Institute of Allergy and Infectious Diseases* (NIAID). The responsibility for program planning is the function of the Director's senior staff group which meets weekly and consists of the Director and his Special Assistant, the Director of Intramural Research, the Associate Directors for Extramural Programs and for Collaborative Research, the Executive Officer, and the Chief, Program Planning and Projection Staff. This group reviews major program plans and arrives at the major program decisions. However, much of the preliminary discussion and assessment is delegated to elements of the three main program areas: Intramural Research, Collaborative Research, and Extramural Programs.

For intramural programs, a major committee that functions in the planning area is the Board of Scientific Counselors, which is composed of non-NIH senior scientists. *Ad hoc* committees (which may include members of the Institute staff, a member of the Board of Scientific Counselors, and others) are also used to provide program planning advice.

In Collaborative Research, there are four advisory committees (Arboviruses, Research Reagents, Vaccine Development, and Transplantation Immunology). These are composed of from six to ten distinguished Federal and nonfederal scientists who serve staggered four-year terms. For this program area, there is also a Contract Review Group, consisting of the Institute Director, his Special Assistant, the Director of Intramural Research, the Associate Directors for Collaborative Research and Extramural Programs, and the Executive Officer.

For the extramural program area, the organization responsible for information for program planning is the Program Evaluation Branch. A new unit—Program Planning and Projection Staff—has just been established (June 1966) in a modest way with one professional. It is expected that this unit will begin to assume a key role in coordinating and formalizing program planning and research projections for the entire Institute. Evaluation of existing programs will continue to be a primary responsibility of the several Associate Directors.

(4) *National Institute of Arthritis and Metabolic Diseases* (NIAMD). The planning function is in the domain of the Director who, in turn, relies on three distinct loci for relevant consultation and planning activities.

The first of these is the Senior Staff of the Institute which meets with the Director on the second and fourth Monday of each month for a three-hour planning and review session. This group is composed of the Director, the Associate Director for Program Analysis and Scientific Communication, the Scientific Director, the Associate Director for Extramural Programs, the Clinical Director, the Executive Officer and Assistant Executive Officer, and the Information Officer. In addition, a similar meeting aimed at planning and review for the Extramural Programs of the Institute alone is held on alternate Mondays. These meetings are attended by the Director, the Associate Director for Extramural Programs and his Deputy, the Associate Director for Program Analysis and Scientific Communication, and the Executive Officer.

In addition, the Office of the Associate Director for Program Analysis and Scientific Communication is specifically charged and executes the planning and program analysis function for the activities of the Institute except where this function is being carried out by other groups for specific programs. This office is composed of the Associate Director, a full-time Program Analyst, and two full-time Program Review Associates.

(5) *National Institute of Child Health and Human Development* (NICHD). The Associate Director for Planning and his two professional staff assistants develop the data needed for planning and formulation of the Institute's goals and objectives, and the means for appraising progress toward these objectives. Efforts are underway to recruit a replacement for the Associate Director for Planning (who is scheduled to retire) and to add two more professional staff.

(6) *National Institute of Dental Research* (NIDR). The Institute Director is responsible for planning. He is assisted in this function by the Institute's Program Planning Office (comprised of two professional and three supporting staff); and by the National Institute of Dental Research Executive Committee. This latter consists of the Associate Director for Extramural Programs, Associate Director for Intramural Research, Associate Director for Special Programs, Program Planning Officer, and the Executive Officer.

(7) *National Institute of General Medical Sciences* (NIGMS). The programs of the NIGMS are planned through actions of in-house and Council committees. The in-house committee is composed of a group of individuals representing three areas of program development: (1) A Scientific Directorate composed of senior and scientific staff of the Institute including the Director, the Assistant and Associate Directors, the Grants Branch Chiefs, the Grants Management Officer, and the Executive Officer. (2) A series of program directors engaged in the development of specific fields in all areas of Institute activity including research, research training, and fellowships, as well as contract negotiations. At the moment there is a program director for comparative animal medicine, a program director for biomedical engineering (acting), a program director for pharmacology and toxicology (acting), and positions are being established for a program director in the behavioral sciences and possibly in the clinical sciences. Other program director positions will be established as the necessity dictates. (3) A group of principal consultants who are senior, nationally-known scientists in their own right who spend from a few months to one year, full or part time in the Institute, developing programs in their specific area of competence. Present principal consultants include Dr. Emanuel M. Papper, Columbia University, Anesthesiology; Dr. George Jordan, Baylor University, Surgery; Dr. Vincent Collins, Baylor University, Radiology; and Dr. John Jacobs, Northwestern University, Biomedical Engineering. Positions anticipated and/or which are in the preparation are consultants in pharmacology (candidate selected), behavioral sciences (candidate identified), and human genetics. It is in the use of these three mechanisms that selected individuals from groups (2) and (3) are brought together with group (1) in order to develop programs.

(8) *National Institute of Mental Health* (NIMH). Primary responsibility for formal planning functions of the National Institute of Mental Health have been assigned to the Office of Planning. The mission of this Office has recently been recast from one of defining the general parameters of future missions to a responsibility for intermediate to long-range planning of program activities. A total of 14 positions (9 professional and 5 clerical) have been budgeted for fiscal year 1967 for the Office of Planning. At present, however, only two professional and four clerical postions are filled, and actions are in process for employing a Chief for the Office and one additional professional level person.

Shorter term planning continues to be the primary responsibility of operating officials throughout the organization. Their activities are coordinated through the Director's advisory staff which consists of the five Associate Directors (program operating heads), the Assistant Director, and the Executive Officer of the Institute.

(9) *National Institute of Neurological Diseases and Blindness* (NINDB). The main responsibility for the planning function is assigned to the NINDB Directorate composed of the Director, Assistant Director, Associate Director for the Extramural Program, Acting Associate Director for the Intramural Program, Director of the Perinatal Research Project, Special Assistant for Program Analysis, Information Officer, and the Executive Officer who is Executive Secretary of the Directorate. No positions are currently vacant. In addition to the NINDB Directorate, there has been established within the Office of the Director a Section of Program Analysis.

(10) *Division of Research Facilities and Resources* (DRFR). The in-house committee primarily responsible for Division planning functions is the Standing Committee of Branch Chiefs. Assigned to this committee are the Chief of the Division, the Assistant Chief, and the Chiefs of the Division's five branches—the Animal Resources Branch, the General Clinical Research Centers Branch, the General Research Support Branch, the Health Research Facilities Branch,

and the Special Research Resources Branch. Two vacancies exist on this committee. The titles associated with these two vacancies are the Assistant Chief for Programs and the Program Analysis Officer.

(11) *Division of Regional Medical Programs* (DRMP). Main in-house planning responsibilities are assigned to the Planning and Evaluation Branch. This Branch, in addition to an Office of the Chief, has a Planning Unit, an Evaluation Unit, and a Studies Unit. Planned staffing calls for 14 professional and six clerical personnel. Of this total, all but two professional and three clerical positions are filled.

Question: "(c) What programming and planning functions are performed by the Committees or groups identified in paragraph (b)."

Responses:

(1) *National Cancer Institute* (NCI). The major program leaders and the Scientific Directorate perform the continuous planning functions necessary for the effective and efficient operation of the Institute's total effort. In addition, certain areas of cancer research, in which the information base and technology have reached a high level of maturity, are selected for more formalized and systematic planning into integrated and coordinated programs with specific disease objectives. In these instances, NCI senior scientists, the Associate Director for Program, and the Program Planning Officer—with the advice of outside experts in the particular field—will formulate a total program plan for implementation.

(2) *National Heart Institute* (NHI). Two principal planning areas are involved: (1) Direct programs (Collaborative Studies, the Comprehensive Blood Program, Erythropoietin, Urokinase Studies, Artificial Heart Program) and (2) Research and Training Grants Program. Each of these activities has planning bodies appropriate in scope for the program-size, the stage of program development, and the aim of the program. For example, a major component of the artificial heart program employs rigorous, systems-analysis planning by in-house staff; the Urokinase program planning is conducted by a small in-house staff with a frequently convened permanent committee of outside participants and advisors.

(3) *National Institute of Allergy and Infectious Diseases* (NIAID). For the intramural area, the Board of Scientific Counselors meets two or more times per year and assists the Director of Intramural Research and the Institute in reaching decisions on broad program plans and on methods of attaining these goals. For example, the Institute's plan to adjust facilities, personnel, and funding to initiate intramural research on hepatitis was placed before the Board for consultation before an Institute decision was made. Similarly, Board advice was obtained on the Institute's plan for reorganization of the laboratory administrative structure concerning the facilities and personnel devoted to research on bacterial and mycotic diseases. Currently, the Board is assisting Institute planning with respect to the amount and type of program emphasis on disease of viral origin.

For the collaborative research area, each of the four advisory committees meets two to four times a year to reexamine the goals of their respective programs. By review of progress made by contracts and by review of new contract proposals, they help to integrate existing and proposed work into a directed, coordinated program. The recommendations of these advisory committees are made to the Director through the Associate Director and the respective Branch Chiefs. The NIAID Contract Review Group establishes policy and ensures adherence to long range goals as well as a balance in the Institute commitments by reviewing all recommendations made by the Committee regarding contract proposals.

(4) *National Institute of Arthritis and Metabolic Diseases* (NIAMD). The Senior Staff or Directorate group plans with the Director overall Institute program goals, primarily in the extramural and collaborative areas. The Office of the Associate Director for Program Analysis and Scientific Communication analyzes and reviews the Institute's ongoing programs, the respective state of the art in the various fields of responsibility of the Institute, and makes recommendations to the Director concerning desirable new programs and plans. In addition, the Associate Director for Program Analysis and Scientific Communication, plans with the Director and in concert with the Directorate, specifically concerning the Institute's collaborative studies and activities.

(5) *National Institute of Child Health and Human Development* (NICHD). The office of the Associate Director for Planning is assigned these functions:

Liaison with the NIH Office of Program Planning.

Analysis of the nature and dynamics of the emerging problems within the broad fields of child health and human development.

Assessing the state of the art and knowledge in each of the relevant areas, and identifying major gaps in knowledge and research needs.

Recommending goals and objectives.
Identifying data needs.
Evaluating program progress and effectiveness.
Preparing and maintaining a comprehensive multi-year program and Financial Plan.

(6) *National Institute of Dental Research* (NIDR). The Program Planning Office is primarily concerned with the compilation and analysis of program data and information required for planning purposes. The Executive Committee assists the Director in exploring, developing and formulating programs and plans.

(7) *National Institute of General Medical Sciences* (NIGMS).—Each of the Institute planning groups operates in essentially the same manner so that the description of the operations of one group (anesthesiology) will suffice for a description of all groups. Anesthesiology was identified by the senior staff of the Institute, the Congressional Committees, and the medical groups around the country as a major discipline requiring stimulation and growth. With this objective in mind a principal consultant was retained, an individual was identified as program administrator within the Institute, and meetings were held with members of the staff and consultants regarding the present level of programs in research and training within the Institute. A major conference calling together senior scientists throughout the country was held to determine the major directions of growth. From the total experience a series of position papers were prepared outlining the general procedures to be followed. Discussions were held with the Division of Research Grants and the Office of the Director, NIH, regarding referral of applications in order to achieve maximum impact. The most competent groups in the country were invited to submit applications in the area of program interest including new lines of attack recommended by the groups mentioned above. For example, the area of patient monitoring and automated anesthesia were stressed. In order to assure that the applications regardless of the area were of high quality, the usual dual mechanism of review was used. Stimulation was thus afforded in all areas of Institute interest.

(8) *National Institute of Mental Health* (NIMH). The Office of Planning serves primarily in a staff capacity to the Director and is the Institute's focal point for planning activities. It is responsible for (1) obtaining information through appropriate Institute and other resources about the programs of the Institute and mental health activities of other federal agencies, state and local agencies, educational and other institutions and professional organizations; (2) appraising information to identify program needs, gaps in current programs, and emerging problems and trends which will influence the course of program development; (3) developing and recommending formal comprehensive proposals for implementation of programs, plans and goals, with alternatives where appropriate, indicating where new courses of action are required or desirable such as new legislation, budgetary changes, reallocation of Institute resources; (4) maintaining current definitions of program goals and objectives reflecting the decisions of the Institute Directorate; (5) recommending to the Director the most appropriate ways for developing intermediate and long-range program plans (e.g., use of Institute Task Force or other staff resources) and at the discretion of the Director assuming responsibility for such activities to assure expeditious action; (6) devising concepts for comprehensive systems to guide the Institute's planning operations and the development of planning resources; and (7) developing and recommending methods for evaluation and determination of program priorities.

These functions are closely coordinated with those of the Office of Inter-Agency Liaison and the Office of Program Analysis, as well as with other appropriate staff and operating components of the Institute.

(9) *National Institute of Neurological Diseases and Blindness* (NINDB). The NINDB Directorate actively plans the Institute's overall program while certain of the individual members develop the specific details of the projects which make up the Institute's program. The section on program analysis provides a facility for the analysis of special problems and questions which arise relating to the mission of the NINDB.

(10) *Division of Research Facilities and Resources* (DRFR). The program and planning functions of the DRFR Standing Committee of Branch Chiefs are to review the accomplishments, needs, and opportunities that evolve out of the ongoing programs of each Branch and to provide continuing re-examination of ongoing Branch activities. In addition, the committee reviews the programs of the Branches and of the Division as a whole in the light of information that is forthcoming from other NIH divisions and Institutes.

(11) *Division of Regional Medical Programs* (DRMP). The Planning and Evaluation Branch is assigned these functions: (1) Develops means and directs activities for appraising Division policies and programs, and progress made toward overall goals and objectives, (2) directs the analysis of information relating to or affecting the program, and advises the Division Chief concerning operational and policy implications, (3) in compliance with Section 907 of Public Law 89–239, prepares and maintains listings of medical facilities where training and medical care of excellent quality are available, (4) provides analytical and interpretive reports of program accomplishments, including the report to Congress required by Section 908, (5) designs and carries out studies on characteristics, sources of support, trends, projections and needs of the regional medical programs, and (6) facilitates the coordination of planning for regional medical programs with other Federal programs in heart, cancer, stroke, and related diseases.

Question: "(d) What major programs are being implemented as a result of such Institute or Division action."

Responses:

(1) *National Cancer Institute* (NCI). Two major program efforts have been planned and implemented as a result of joint planning efforts described in this document: The Special Virus-Leukemia Program, and the re-planning of the Cancer Chemotherapy Program. In addition, initial planning efforts have been made for the purposes of formulating a major coordinated and integrated research effort in breast cancer. These initial plans are now being considered by a Breast Cancer Task Force for further development.

(2) *National Heart Institute* (NHI). Major programs implemented are (1) Comprehensive Blood Program, (2) Urokinase Program, (3) Artificial Heart Program, (4) Hawaii-Japan cardiovascular epidemiology project, (5) Puerto Rico cardiovascular epidemiology program, (6) Framingham project, etc.

(3) *National Institute of Allergy and Infectious Diseases* (NIAID). Major programs implemented through Institute planning processes include:

Virus Reagents Program—production, testing and distribution of a broad series of viral seeds and antisera.

Vaccine Development Program—development of inactivated, attenuated and viral subunit vaccines and their evaluation in the prevention of diseases, particularly respiratory diseases.

Transplantation Immunology—development of methods and resources, especially antisera, needed for the identification and characterization and purification of transplantation antigens with the long-range goals of facilitating research in organ transplantation.

(4) *National Institute of Arthritis and Metabolic Diseases* (NIAMD). The best example of a planned program is the Institute's Artificial Kidney—Chronic Uremia Program, a mission-oriented, planned and centrally directed research and development activity aimed at the improvement of artificial kidneys and related methodologies for the permanent maintenance of patients with chronic renal failure. This is a major program involving between four and five million dollars in research and development contract money in fiscal year 1967, as well as direct basic and clinical research by staff members in collaboration with other Government agencies.

Another example would be the National Pituitary Agency, an organization created through Institute planning by contract, for the collection of human pituitary glands, extraction therefrom of human growth hormone and other highly important hormonal fractions and their selective allocation for fundamental and clinical research.

A third major program systematically planned and executed by NIAMD is the Institute's large scientific communication activity, comprised at the present time of three major monthly publications, "Arthritis and Rheumatic Diseases Abstracts," "Diabetes Literature Index," and "Gastroenterology Abstracts and Citations"; and a quarterly publication, "Kidney Failure and Artificial Kidney Bibliography." Here again, as in the case of the Artificial Kidney Program and the National Pituitary Agency, analysis of the state of the art pinpointed the need for the ultimate activity and resulted in systematic planning and rapid rapid execution of the program.

(5) *National Institute of Child Health and Human Development* (NICHD). A major effort of the Associate Director for Planning has been a systematic analysis of the training needs for Institute areas of research responsibility in order to identify long-range manpower objectives and to determine how best to meet these objectives.

(6) *National Institute of Dental Research* (NIDR). Planning accomplishments include: the extablishment of Dental Research Institutes in a number of university environments; and the re-alignment of the extramural organization and operation on a scientific categorical program basis. This assures that for each program area, research, training and resource needs are viewed as parts of an inter-related whole, rather than as separate problems to be dealt with independently of each other.

(7) *National Institute of General Medical Sciences* (NIGMS). Using Institute planning mechanisms, major impetus is being applied in the fields of: Diagnostic Radiology, Surgery, Biomedical Engineering, Anesthesiology, Pharmacology and Toxicology, Laboratory Medical Sciences, Genetics, the Behavioral Sciences, and Comparative Animal Medicine.

(8) *National Institute of Mental Health* (NIMH). Professional staff of the Office of Planning in recent months have engaged in planning functions primarily through participation with program operating officials. During the past year these have been largely concerned with intergovernmental activities including exploration of the Institute's role in Medicare, Appalachia programs, youth opportunity, poverty, and urban affairs.

(9) *National Institute of Neurological Diseases and Blindness* (NINDB). Major programs being implemented as a result of NINDB Directorate and Program Analysis activity include the following: Expanded programs in deafness, vision, and stroke research; development of a collaborative study in epilepsy; the establishment of a national study of head injury; and intensified program in a search for the virus etiology of chronic degenerative diseases of the nervous system; and the development of a laboratory of neurological control and a branch of neuro-otolaryngology within the intramural program of the Institute.

(10) *Division of Research Facilities and Resources* (DRFR). As a result of Division planning activities, several major programs have been implemented. These programs include the Biomedical Sciences Support Grant program, which extends to graduate institutions the same type of general support that was previously limited to health professions schools and non-academic institutions; and the Health Sciences Advancement Award program, which provides an opportunity for additional graduate academic institutions to raise the status of their biomedical research programs. Also, a special research resource program has been started to provide analytical biochemistry instruments such as mass spectrometers and nuclear magnetic resonance spectrometers.

(11) *Division of Regional Medical Programs* (DRMP). The major initial activities of the Planning and Evaluation Branch include the following:

(1) The production of the report (to the President and Congress) required under Section 908 of P.L. 89–239.

(2) The development of a planning process whereby the national program goals of the Division of Regional Medical Programs are specifically articulated, interpreted and projected into the future and coordinated with related planning programs.

(3) The tentative identification and application of yardsticks for measurement of progress toward the established program goals and the collection and analysis of data measuring the progressive status of program actions toward accomplishment of the program mission.

Question: "(e) Which Advisory Councils for the nine Institutes and four divisions of NIH have established Subcommittees for planning or have similar means by which they assist in planning."

Responses:

(1) *National Cancer Institute.* The National Advisory Cancer Council has two subcommittees: the subcommittee on Diagnosis and Treatment, and the subcommittee on Carcinogenesis and Prevention. Currently, there is no specific subcommittee for planning, however, these two subcommittees function as review and advisory bodies for the research supported and conducted by the Institute in these two major areas and advise the full Council and the Director on total program matters with respect to coverage, emphasis, and new and important research opportunities in these major areas.

In May, a special *ad hoc* committee of Council and NCI staff members met to discuss ways of improving program review and the planning function of the Institute in general, and also ways in which the Council itself could best participate in any expanded planning function. As a result, this *ad hoc* committee will recommend to the Council, at its June meeting this year, that a Council subcommittee for Planning be established. In addition, a special *ad hoc* Committee on Policies and Procedures recently met to discuss ways of improving the material and information on program reviews provided to the Council.

(2) *National Heart Institute.* The NHI Advisory Council has a "Planning Committee" consisting of four Council Members.

(3) *National Institute of Allergy and Infectious Diseases.* The Council for this Institute has four subcommittees that are responsible for formulating the presenting program plans to the Council: Manpower Subcommittee; Transplantation and Immunology Subcommittee; Chronic and Degenerative Diseases Subcommittee; and Viral Chemotherapy Subcommittee.

(4) *National Institute of Arthritis and Metabolic Diseases.* The National Advisory Arthritis and Metabolic Diseases Council has had a planning subcommittee for many years.

(5) *National Institute of Child Health and Human Development.* The National Advisory Child Health and Human Development Council has a Committee on Planning and Agenda which consists of five Council members. It was established in 1964.

(6) *National Institute of Dental Research.* The Program Planning Committee meets three times a year. Its meetings last from two to three days. Minutes and recommendations are prepared for presentation to the Council and the Institute.

(7) *National Institute of General Medical Sciences.* The meetings of the Planning Subcommittee usually take several hours, preceding each Council meeting. The recommendations are often coupled in two ways: (1) a member of the Committee makes an oral report to the Council in his area of interest, (2) the member may also have participated in a major conference in his program area, often serving as chairman, so that the report of this conference group may also serve as his report to the Council.

(8) *National Institute of Mental Health.* The NIMH Council has not yet established a formal planning committee.

(9) *National Institute of Neurological Diseases and Blindness.* The Council subcommittees and committees meet with varying frequency depending upon the need. Usually no less than three times per year but in certain instances more frequently. The length of time of meetings is from one to three days. Short progress reports from each of the groups is presented at each meeting of the National Advisory Council. Written reports, usually of some length, are compiled of the studies of these committees and subcommittees and constitute documents of value to the Institute and to the scientific community in planning programs of research and research training.

(10) *Division of Research Facilities and Resources.* Subcommittees meet regularly before each council meeting—three times a year. Subcommittee meetings last from two to four hours and there is no fixed format. Any additional meetings during the year would only be held at the discretion of the chairman of the Council.

(11) *Division of Regional Medical Programs.* Not applicable.

Question: "(f) The frequency and length of time of the meetings of such Subcommittees and the format used in presenting their recommendations for new programs to the Council and in turn to the Institutes."

Responses:

(1) *National Cancer Institute.* The two currently established Council subcommittees meet at least three times a year in phase with the full Council meetings. The length of these subcommittee meetings is typically one or two days in which members review and discuss ongoing NCI programs and plans in the respective areas of carcinogenesis and prevention, and diagnosis and treatment. In addition to the regular Council meetings, a special meeting of the full Council is held, usually in October, for the purposes of program reviews. At these meetings, leaders of the major NCI programs describe their total program effort to the Council not only for purposes of review but for purposes of identifying major areas in which further planning may be appropriate.

Typically, the respective subcommittees of the Council will have reviewed the major program of the Institute in their areas prior to the full Council meeting and present their assessment and recommendations regarding these programs to the full Council.

(2) *National Heart Institute.* The Planning Committee to the NHI Advisory Council meets regularly one month prior to each Council meeting and occasionally on an *ad hoc* basis as well. The meeting usually lasts one full workday.

(3) *National Institute of Allergy and Infectious Diseases.* By making specific program areas their special concern, the four Council subcommittees have, with the help of staff, focused the attention of Council on program needs and possibilities in these areas and gained full Council support for necessary implementing action.

The Manpower Subcommittee replaced the Training Panel of Council which

has reviewed the training programs of this Institute for the past several years. They usually meet once a year for one day. They search out weak points in the program and advise the Council and staff on ways of correcting these defects.

The Transplantation Immunology Subcommittee met twice in 1964, for approximately one day at each session. A resolution presented to the June NAAIDC was adopted, in expressing concern that respect of ethical and moral human rights should be observed closely by workers, and that all relevant animal and other studies should be undertaken before undertaking transplantation in man. This subcommittee, together with *ad hoc* consultants, also established the areas of priority in the field of transplantation immunology that were used for grants analysis work by the Institute and the entire NIH.

The Subcommittee on Chronic and Degenerative Diseases of microbioal origin met twice in 1964 for about one day at each meeting. A resolution was adopted by the June 1964 NAAID Council to develop plans for promoting research on these diseases, indicating this as a major program objective of this Institute. A meeting of the subcommittee in October 1964 was followed by a presentation to Council summarizing current research knowledge. To implement the decisions of Council, in 1965 the NIAID staff held four separate meetings in the U.S. on this subject. Additional visits were made to important European centers engaged in relevant research. Programming developed rapidly from these massive efforts with the quick acknowledgement of the high potential for very important research developments by the scientific community concerned. Progress reports have been made regularly to the Advisory Council and programming continues productively.

The Viral Chemotherapy Subcommittee met twice in 1964 for about one day each meeting. It presented a resolution which was adopted by the NAAID Council in June 1964, resolving that a review of recent progress be undertaken to determine means of promoting research in viral prophylaxis and viral chemotherapy.

(4) *National Institute of Arthritis and Metabolic Diseases.* The Planning Committee of the Council meets with the Director (and the Associate Director for Extramural Programs and his Deputy, and the Associate Director for Program Analysis and Scientific Communication) on the day preceding the three-day meetings of the Institute's Advisory Council. Planning subcommittee meetings usually last for three hours and take place three times each year. During these meetings the Director reviews past and ongoing activities and consults with the planning subcommittee concerning recommendations for new programs pertinent to the Institute's mission. In turn, the planning subcommittee and its members make proposals concerning program emphasis and new directions to the staff. These planning recommendations are not necessarily limited to the extramural program of the Institute. Subsequently, the third day of the ensuing three-day council session is devoted to a review, by the Director and Senior Staff, of past and ongoing programs before the Council as a whole, and to presentations by members of the planning subcommittee, as well as to general discussion by the Council as a whole, of future program plans.

(5) *National Institute of Child Health and Human Development.* The Committee on Planning and Agenda has at least one formal meeting, lasting about half a day, which takes place within the month prior to each scheduled meeting of the Council. The Committee Chairman, one of the five Council members on the Committee, reports on the deliberations and recommendations of the Committee to the full Council for discussion and appropriate action. This is done in the opening session of the Council meeting and constitutes a regularly scheduled item on the agenda. The Council's actions on the report of the Committee are recorded in the formal minutes of the meeting. The Institute carefully considers Council reaction to the Committee report.

(6) *National Institute of Dental Research.* The National Advisory Dental Research Council has a Program Planning Committee to assist the Council and Institute in planning.

(7) *National Institute of General Medical Sciences.* The National Advisory General Medical Sciences Council has always had a planning committee consisting of the entire Council which routinely meets the night before the regular Council meeting and at other intervals when the Director, NIGMS, deems it necessary. This Committee is fully informed of the programming efforts of the Institute and of the actions of the in-house advisory groups. Members of the Committee are identified with particular areas of programming interest (Dr. Rhoads—Surgery and Trauma, Dr. Kinney—Radiology and Medical Laboratory Science, Dr. Beadle—Genetics, Dr. Lowry—Pharmacology, etc.).

(8) *National Institute of Mental Health.* The NIMH Council has not established a formal planning committee but has held some preliminary discussions

pertinent to its more active participation in the planning of programs and in the development of budget proposals. To date the Council's participation in the planning of new programs has been largely advisory. However, it has been instrumental in bringing focus to bear on planning in specific problem areas such as the development of support for a planning mission concerning the problems of childrens' emotional illnesses. A grant has been awarded for support of a Joint Commission for a two-year period for a program of research into and study of resources, methods and practices for diagnosing or preventing emotional illness in children and of treating, caring for, and rehabilitating children with emotional illnesses.

(9) *National Institute of Neurological Diseases and Blindness.* The National Advisory Council on Neurological Diseases and Blindness has set up several advisory committees. The first of these was the Joint Council Subcommittee on Stroke which was organized in cooperation with the Advisory Council to the National Heart Institute. More recently the Advisory Council has set up an *ad hoc* Committee on Vision and Visual Disorders and an *ad hoc* Committee on Human Communication and its Disorders. In addition, there has been formed a national advisory committee on the epilepsies and an advisory committee on head injury.

(10) *Division of Research Facilities and Resources.* The advisory councils for DRFR that have planning committees are the National Advisory Health Council with a subcommittee for general research support, the National Advisory Council for Health Research Facilities with a program planning subcommittee, and the National Advisory Research Resources Committee with a program planning subcommittee.

(11) *Division of Regional Medical Programs.* No planning subcommittees established as yet. The Council met for the first time December 1965.

Question: "(g) What major recommendations have been made and programs inaugurated within the past few years as a result of such planning efforts."

Response: The inauguration of major new programs by NIH Institutes and Divisions invariably reflects some degree of planning and advisory input from both in-house and Council groups. Therefore, the recommendations and programs described in response to question (d) might appropriately be cited again in this response. These additional examples of Council impact on planning processes are illustrative of many others that could be offered:

(1) *National Heart Institute (NHI):* Over the years a number of programs have emerged from the recommendations of the Council Planning Committee; some have become "direct-operations" programs, others have become grant-supported programs. Through the initiation of the National Advisory Health Council Planning Committee, the NIH Regional Primate Centers Program and the MEDLARS Activity of the National Library of Medicine were implemented and financed. Several collaborative research programs were so initiated. For example, the "Diet-Heart Disease Feasibility Studies," the "Cooperative Study of Drugs and Coronary Heart Disease," "Extracranial Vascular Occlusion Study," "Renovascular Hypertension Study," "Cooperative Cardiovascular Surgery Study," etc.

(2) *National Institute of Neurological Diseases and Blindness (NINDB):* Major recommendations made by the National Advisory and Council Subcommittees within the past few years include the following: (a) A comprehensive report and recommendations on stroke which have been the basis for the Institutes' development of its expanded and long-term program in research and training in cerebrovascular disease; (b) A report and recommenations of the committee on head injury which is forming the basis of the Institute's national program on head injury: (c) A staff report by a visiting scientist describing the state of knowledge and the research needs in the field of the epilepsies. This is also being implemented by a collaborative study of epilepsy in several medical centers; (d) A recommendation of the Council Subcommittee on Human Communication and its Disorders that a branch of neuro-otolaryngology be established within the intramural program of the Institute.

(3) *Division of Research Facilities and Resources (DRFR):* The Health Sciences Advancement Award Program was recommended by the subcommittee for general research support of the National Advisory Health Council. This program has been inaugurated and will provide an opportunity for more institutions to advance the status of their research and research training in the health sciences. In addition, the General Research Support Branch of DRFR has developed a position paper on the need for flexible general institutional support funds for schools of nursing. This paper was developed in conjunction with the General Research Support Scientific Advisory and Review Committee. The position paper has been sent forward to the National Advisory Health Council for their consideration and possible action.

Part 6—Excerpts From Report to Subcommittee on HEW Investigation, Committee on Interstate and Foreign Commerce, House of Representatives, on the Review of Awards Under the Research Career Program, National Institutes of Health, Public Health Service, Department of Health, Education, and Welfare, by the Comptroller General of the United States, April 1966

"In our review of awards made under the Research Career Program to six institutions in support of 73 individual awardees, (amounting to about $4.3 million as of June 30, 1965), we found a total of 43 instances of deficiencies or questionable practices in one of the following respects: (1) the extent of academic course work and administrative activities appeared too substantial, (2) the retention by awardees of income from outside sources appeared to be contrary to or questionable under the terms of the grant, (3) payments from institutional funds to awardees appeared questionable, (4) awardees were paid salaries in excess of approved amounts, and (5) propriety of certain awards appeared doubtful. One or more of these deficiencies or questionable practices were found with respect to each of 37 individual awardees, including awardees at each of the institutions covered by our review.

"We believe that most of these matters, . . . may be attributed to a lack of clarity in the NIH policies governing the Research Career Program and to the fact that the National Institutes of Health do not require awardees and grantee institutions to provide adequate information regarding awardees' outside income, the nature of awardees' activities, and the use of fees remitted to the institutions by the awardees.

"Distribution of Awardees' Time and Effort

"Our review at the six grantee institutions indicated that the majority of the Research Career Program awardees were then spending at least 80 percent of their time on research or research-related activities. The awardees' remaining time was spent primarily in teaching, with small amounts of time devoted to administrative activities, scientific meetings, outside lectures, and private and clinical consultations. Three awardees, however, had devoted a large portion of their time to the pursuit of academic courses although it is not clear from the regulations or agreements whether such pursuit can be considered research or research-related activity. Another awardee had spent a major part of 1 year in connection with duties as president of a national health association. In these cases, it appeared that NIH had not been fully informed of the nature and extent of these activities by the awardees.

"We obtained information concerning distribution of time and effort for 67 of the 73 awardees included in our review. The other six awardees had transferred to other institutions prior to our review. Inasmuch as detailed records giving a breakdown of time were not maintained by the awardees or the institutions, we obtained information in this regard primarily through discussions with the awardees and cognizant institutional officials but were unable to independently verify the accuracy of the information.

"NIH policy states that Research Career Program awards are intended to provide institutions with funds to compensate awardees adequately for full-time research and research-related activities; awardees should not engage in clinical practice, professional consultation, or similar work unless these activities are required by their research and teaching or are necessary to maintain their professional skills. They may, however, engage in such activities as scholarly writing, service on advisory groups, and delivery of outside lectures provided these activities remain incidental and are undertaken within institutional policy.

"We found in our review that three of the awardees at University A were enrolled as full-time students during the period in which they were receiving stipends under the Research Career Program. Information concerning the activities of these awardees follows:

"*Awardee A*—Awardee received research career development awards for calendar years 1962 and 1963 providing for basic salary support of $13,250 each year. . . . The awardee claimed that 90 percent of his time was devoted to accomplishing the course work and research requirements for the Ph.D. degree. Also, an official of University A certified . . . that during calendar years 1961, 1962, and 1963 the awardee was registered as a full-time graduate student working toward his Ph.D. degree. This awardee's support under the research career development program

terminated on December 31, 1963. He advised us in November 1965 that 90 percent of his time had been spent in research and 10 percent in teaching.

"The awardee received support under the NIH Senior Research Fellowship Program, the forerunner of the Research Career Program, in calendar years 1959, 1960, and 1961; his support was transferred to a career-development-type award in 1962. In the awardee's application under the fellowship program for calendar year 1959, an official of University A estimated that during the first year 50 percent of the awardee's time would be spent in academic course work and personal study. Subsequent progress reports submitted with applications for continued support under the fellowship program for 1960 and 1961 stated that the awardee was taking or had taken courses in physiology, calculus, physical chemistry, French, biochemistry, isotope techniques in medicine, German, and oral biology. The progress report submitted in connection with the awardee's application for support under the Research Career Program in 1963 also indicated that he was engaged in course work and seminars in a variety of subjects.

"*Awardee B*—Awardee received two research career development awards at University A for 1-year periods beginning July 1, 1963, and July 1, 1964. The awards provided for basic salary support of $11,500 and $12,500 per annum. The record indicates that the awardee was in residence at another University (W) Graduate School from September 1963 until June 1964. University W certified that the awardee entered the university in September 1963 and completed three academic quarters of graduate work through June 1964. The awardee advised us in November 1965 that he was currently spending about 35 percent of his time in research, 40 percent in personal development (academic courses), and 15 percent in teaching, professional practice and administration.

"The original application submitted for this awardee for fiscal year 1964 indicated that, in addition to research and teaching, his other activities during the first grant year were to include graduate courses in biochemistry, biochemical instrumentation, and statistics and participation in dental research seminars. Academic course work was also indicated for the second and third years. The progress report summarizing the awardee's activities during fiscal year 1964 showed that he was a resident student engaged in formal course work at University W for 10 months during this period.

"*Awardee C*—Awardee received two research career development awards at University A for 1-year periods beginning July 1, 1963, and July 1, 1964. The awards provided for basic salary support of $11,500 and $12,500 per annum. . . . our examination indicated that he was a full-time trainee at University A from October 1, 1963, through December 31, 1964. . . . In November 1965 this awardee gave us an estimate of his percentage of effort as 45 to 60 percent research, 30 to 40 percent academic courses, and 10 to 15 percent consultation and teaching.

"This awardee's original application for fiscal year 1964 stated in part:

> "* * * If the award is made, he will be able to devote full time to research and research training. It is pertinent that the University * * * has extensive graduate school offerings, and these would be available to Dr. * * *."

"The first progress report for the period July 1, 1963, through March 21, 1964, summarizing the awardee's activities showed that the awardee had taken a 4-week training course at a Federal facility. The progress report for the subsequent period ended March 15, 1965, showed that the awardee spent 3 months in course work at an institution in another city and was completing a graduate course at University A. Neither progress report indicated that the awardee was enrolled as a full-time trainee.

"Information contained in the NIH policies governing the Research Career Program and information obtained during discussions with NIH officials did not clarify the extent to which academic study should be considered as research and research-related activities. Support to individuals requiring additional predoctoral and postdoctoral training is generally provided through the traineeship and fellowship programs of the NIH.

"In view of the lack of clarity concerning the extent of academic study which should be considered as research and research-related activities and in view of the other NIH programs which provide support to individuals requiring additional training, we believe that there is a question of whether it is proper under the Research Career Program to support individuals enrolled as full-time trainees or candidates for degrees, who are devoting a significant percentage of their time to academic study. In regard to an awardee's activities, the terms of award of the program state: '* * * his primary responsibility must be for the conduct and direction of research and research training.'

"One awardee at University T advised us that he was away from the sponsoring institution from 50 to 75 percent of the time during the period October 1, 1964, to October 1, 1965, in connection with his duties as president of a national health association. During this period the awardee received salary support of $25,000 through his career award. He advised us in November 1965 that his tenure as president was now completed and that he was spending about 80 percent of his time in research and 20 percent in teaching, in serving on committees and boards and in administration.

"This awardee's application for support under a career award did not state that he would be away from the sponsoring institution for a significant portion of his time. The progress report submitted by University T showed that the awardee had spent some time in connection with his duties as president of the association but did not show how much time was spent.

"In connection with administrative responsibilities, the terms of award state:

> "Awards will not be made on behalf of persons who will have substantial administrative responsibilities. Nor will awards be continued or renewed if substantial administrative responsibilities are later assumed."

"In view of the substantial administrative responsibilities assumed by this career awardee in October 1964, we believe that the continuation of this grant may have been in violation of the terms of award. Although the terms of award clearly state that awards will not be continued or renewed if substantial administrative responsibilities are assumed after the award is made, there is no requirement that the sponsoring institution promptly report to NIH changes in an awardee's plans or duties which will affect his research effort. As a result there is no assurance that NIH is made aware of such changes and is in a position to enforce the terms of award.

"Compensation Received for Outside Activities, Retained by Awardees

". . . Our examination revealed that 35 awardees reported income from outside sources during 1963 or 1964 or both years. The income reported by six of these awardees appeared to be contrary to the terms of the grant award. For 20 other awardees, . . . information . . . was insufficient with respect to the nature of the service from which the income was derived to permit a determination of whether such income was consistent with the terms of award. . . . Outside income earned by the individual awardees ranged from about $100 to $10,000 per year.

"NIH policy requires that institutions use the Research Career Program award to provide full salary for the awardees. Accordingly, the awardee may not receive additional income for professional services from the institution or from other sources. He may, however, retain honoraria, royalties, and fees for such activities as scholarly writing, service on advisory groups, and delivery of outside lectures, provided that these activities remain incidental and are undertaken within institutional policy.

"Income from outside activities which appeared to be contrary to the terms of award under the NIH Research Career Program was reported by six of the awardees. . . . Although each of the six awardees reported significant amounts of outside income, . . . we found that neither the progress reports nor the applications submitted to NIH in connection with their awards shows that these awardees were engaged in the ourside activities from which they derived income. None of these awardee's applications for fiscal years 1963, 1964, or 1965 contained any reference to disposition of fees, even though the application forms called for specific information on the sponsoring institution's policy in this regard. Further information concerning these six awardees is presented below.

"*Awardee D*—In addition to the salary provided by the research career award, this . . . awardee earned $6,316 in 1963 and $4,998 in 1964 in addition to his basic salary support under the Research Career Program in these years of $10,000 and $12,000, respectively.

"*Awardee E*—This awardee reported income from consultations and professional fees and lectures amounting to $4,000 and $3,000 in addition to salary received under the research career award of $12,114 and $12,945 in 1963 and 1964, respectively. This income was partially offset by reported expenses of $1,730 and $1,875.

"*Awardee F*—Awardee received research career development awards providing basic salary support of $18,000 a year for periods beginning July 1, 1963, and July 1, 1964. . . . this awardee reported private practice income of $10,185 and $10,056, less related expenses of $4,589 and $5,123, in calendar years 1963

and 1964, respectively. We could not determine . . . whether this income, although shown as income from a practice conducted in the awardee's name, resulted solely from the awardee's activities or in part from the activities of his spouse, who is also a physician.

"*Awardee G*—For calendar year 1964 this awardee reported fees amounting to $5,328 in addition to his salary under the Research Career Program of $14,000. The awardee advised us that he had served as a consultant on optical problems and that this work had been performed on his own time.

"*Awardee H*—During 1963 and 1964 this awardee reported salaried income from a State agency of about $3,465 and $2,987, respectively, in addition to the basic salary support of $9,500 and $10,258 provided by the institution in connection with his research career development awards in 1963 and 1964, respectively.

"*Awardee I*—This awardee earned $2,400 and $1,900 during 1963 and 1964, respectively, as a consultant to a Veterans Administration Hospital. . . . During 1964 he received an additional $200 as a consultant to another university. These amounts were in addition to basic salary support of $12,541 in 1963 and $13,541 in 1964 received under the Research Career Program.

"For 20 other awardees, [we were unable to determine whether the reported] income was consistent with the terms of award. . . . these awardees [had] outside income ranging from about $100 to $5,000 a year . . . derived from sources such as consultation, professional activities, professional fees, and duties at other institutions. For several of these awardees, the reported amount of outside income indicated that the time required for these activities may not have been incidental to their research activities.

"For example, one research career awardee reported income of $1,500 from an institution other than the sponsoring institution during each of calendar years 1963 and 1964. This income may have been derived from outside lectures which the awardee reported to number about 20 to 30 a year. The applications and progress reports submitted in connection with this award made no mention of the lectures or of the income received by the awardee.

"Another awardee received outside income totaling $1,250 during 1963 from another university and a professional society. This awardee's progress report stated that he had delivered a series of lectures at another university and had served on a committee of a medical society, but it made no mention of income received for these services.

"We believe that the examples presented above indicate a need for the sponsoring institutions to establish procedures to ensure that individual awardees limit their activities in accordance with the terms of award. In addition, we believe that NIH should require the institutions to include in the annual progress reports detailed statements setting forth the nature and extent of awardees' outside activities and the amounts of income derived therefrom.

"In our opinion, there is also a need for NIH to more clearly define the types of income which may be retained by awardees. In this connection we believe that the conditional language in the present terms of award should be eliminated and specific criteria, setting forth in detail those activities which are permissible and the extent to which such activities may be undertaken, should be established to serve as guidelines in administering awards under the program.

"Income Remitted to Institutions by Awardees

"In our review, we found evidence that 14 research career awardees had remitted income received for professional services to the grantee institutions. Our examination . . . revealed that only two of the [14] awardees reported outside income from fees for professional services in addition to that remitted to the institutions.

"We obtained information from institutional records concerning the amounts of professional fee income remitted to the institutions by seven awardees. This information is shown in the following schedule.

"Awardee	Amount	Period	
		From—	To—
1	$220	Sept. 1, 1964	Aug. 31, 1965
2	4,540	Oct. 1, 1963	June 30, 1965
3	1,343	Apr. 1, 1964	Dec. 31, 1964
4	2,502	July 1, 1964	Nov. 10, 1965
5	1,691	Jan. 1, 1963	Sept. 30, 1964
6	1,296	July 1, 1963	Aug. 31, 1965
7	2,179	----do-------	Do.

"The terms of award concerning disposition of professional fees require that the full circumstances and facts relating to the fees and the policy of the institution relating thereto be presented in the application if it is proposed that the applicant institution or other party retain fees accruing from professional practice by a candidate. Our review of applications submitted for the seven awardees referred to above revealed that in all but one case the institutions stated that the fees would be used for support of various research or academic programs. In the other case, the original application stated that, if collected, fees could be returned to the university or to the PHS, depending on the policy of the latter. Subsequent applications in this case stated that no fees were involved. We were advised by officials at several of the institutions visited that professional income remitted to the institutions was put into special funds and generally used to support the institution's research or educational activities.

"At University A, however, the records showed that payments from professional and other types of funds were made for the benefit, either directly or indirectly, of the individual awardee. Although some of the expenditures were of a type that could have been reimbursed from institutional funds, such as for travel and supplies, a significant amount could not have been; and to this extent it appears that the awardee recipients in effect realized additional income.

"Three of the awardees at this institution were engaged in clinical practice or consultative work, which, according to their applications, was for the purpose of maintaining professional skills rather than for producing income. During the period January 1, 1963, through August 31, 1965, about $4,572 received as fees from practice and consultation by these three individuals was remitted to the university. Also accumulated in their professional funds were $500 for supervision of an industry grant project and $94 for lectures.

"Of the amounts accumulated in professional trust funds to August 31, 1965, about $3,500 was expended for such purposes as travel, dues, membership fees, supplies, tuition and registration, salaries, insurance, general expense, and postage. From a detailed analysis of the expenditures in conjunction with advice from the comptroller at the institution, we ascertained that about $1,200 in effect constituted income to the individual awardees, as shown in the following schedule.

"Purpose	*Amount charged to fund*
Personal travel expenses	$423
Licenses, dues, membership fees, donations, legal fees, etc	256
Malpractice insurance	180
Tuition	309
Total	1,168

"At University A we noted also that grant funds from a private source had been used to supplement an awardee's income. In November 1964, $2,500 was transferred from a private grant fund to institutional funds to support a research career awardee's academic program. According to an institution official, this amount represented the value of services rendered by the awardee on a grant project. The awardee also stated that, although the decision to provide these funds was made 11 months after his NIH grant period began, the services were performed during the period prior to January 1, 1964.

"In connection with the transfer of funds, it was noted that this awardee departed for London late in November 1964 to engage in further studies. The

awardee advised us that these funds enabled him to pay expenses of his family to and from Europe while he was under the NIH Research Career Program. Family expenses could not have been reimbursed from institutional or NIH funds. No mention was made in the institution's progress report to NIH concerning this award, of the transfer of $2,500 from the private grant fund to institutional funds, and of the subsequent use made of the money by the awardee.

"In addition, our review disclosed that one awardee at University A won a private foundation grant of $30,000 payable over a 5-year period as a Scholar in Academic Medicine. An institution official advised that expenditures from the private grant award, which runs concurrently with the NIH award, would be managed in accordance with the institution's policies governing expenditures from professional funds. At the time of our review, only minor expenditures had been made from this fund. However, as noted in our discussion of disposition of fees . . . [above], existing policies at University A would apparently permit the payment of personal-type expenses from this fund which could not otherwise be paid from institutional funds.

"We found no information in the files indicating that NIH had been advised of the receipt of the $30,000 award by this awardee.

"We believe that our findings indicate a need for NIH to establish a more definitive policy regarding the disposition of fees earned by awardees. If it is determined that the retention of the fees by the institutions is in the best interests of the Government, we believe that NIH should require the institutions to include in their annual progress reports a detailed statement of the manner in which fees accruing from professional practice and other activities of awardees have been used. In our opinion there is also a need for NIH to establish a definitive policy regarding the types of support, e.g., equipment and supplies to which funds obtained from other sources may be applied in connection with the Research Career Program.

"Awardees Paid Salaries in Excess of Approved Amounts

"At University C we found that 6 of the 15 individual awardees were paid salaries in excess of those approved in the fiscal year 1964 grant awards. The terms of award require that the sponsoring institution indicate the salary it proposed to pay the candidate from the grant and use the award to provide full salary for the awardee. The terms of award also state that an awardee may not receive additional income for professional services from the institution or from other sources and that any salary increase requested must be justified. We found no indication that the grantee institution had requested approval from NIH to increase the awardees' salaries above those proposed in the applications or that it had justified the increases.

"The following schedule lists the salaries proposed by University C in the grant applications approved by NIH and the salaries paid to the awardees by University C.

"Awardee	Amount of awardee's salary		
	Approved by NIH	Paid by institution	Additional amount
1	$15,800	$16,600	$800
2	12,900	13,600	700
3	10,600	11,100	500
4	9,900	10,400	500
5	12,200	12,417	217
6	11,970	12,000	30

"These additional salaries, which resulted from university wide salary or individual merit increases, were paid without prior approval by NIH from PHS general research support grant funds, other PHS grant funds, or Research Career Program award funds provided the institution by NIH to cover fringe benefits or indirect costs related to the grants.

"University C used $1,406 of funds provided by a PHS general research support grant to pay a part of the additional salaries of three of the awardees. While PHS general research suport grant funds may be used to cover administrative salary increases to employees at an institution, funds from this type of grant are not intended for providing additional salary for individuals supported under pro-

grams, such as the Research Career Program, which limit awardee's to amounts provided under the grants.

"Funds to pay the remaining part of the additional salaries consisted of $416 which had been included in the research career grants to cover the institution's indirect costs and fringe benefits and $925 from a PHS mental health training grant awarded to University C.

"We noted that in certain cases NIH had made supplementary awards under the Research Career Program to cover institution wide salary increases on the basis of applications from the institutions justifying the increases. We believe, however, that the payment of additional salaries * * * is questionable under the policies governing the Research Career Program. In particular, we believe that, under the Research Career Program, the use of grant funds awarded for general research support, training, and nonsalary costs to pay the additional salaries is not in accord with the purposes for which the grants were made.

"Questionable Propriety of Certain Career Development Awards

"We found that three awardees who are currently recipients of career development awards apparently considered themselves, and were considered by their sponsoring institutions to be, qualified and established investigators of high competence, as evidenced by the fact that the sponsoring institutions, on behalf of the three awardees, had first applied for support through career awards. When NIH elected to curtail the career award program beginning in fiscal year 1965, applications for awards under the career development program were substituted. Two awardees' career development awards were extended for an additional 5-year period and the other individual was granted a 5-year development award in lieu of the career award.

"In an appearance before the Committee on Appropriations, House of Representatives, in February 1965, the Director, NIH, indicated that it was decided not to expand the career award program because of the adverse effect the program was having on relations between awardees and grantee institutions and because funds were not available to support additional awardees. Also, the Director stated:

> "One factor that led to our termination of this program was that fluid support became available in the form of the institutional general research and training grants which can in fact be utilized to pay such salaries."

"In commenting on career development awards, the Director, NIH, stated:

> "It was envisioned—and it is still envisioned—that this program will provide candidates for the selection of future faculty."

"NIH policies state that development awards are available for (1) individuals with clear research potential who require additional training and experience in a productive scientific environment in preparation for careers in independent research and (2) individuals with demonstrated capacity for independent research who have not yet reached the stage in their scientific development to qualify as candidates for career awards.

"Career awards enable institutions to finance positions favorable to the intellectual growth and research productivity of established investigators of high competence for the duration of their careers. These awards were made on the basis of nationwide competition among candidates whose research had won the respect of scientific leaders in their fields.

"Our review of the files pertaining to one awardee who was granted a 5-year extension of his development award disclosed that at the time of application for the extension the awardee (1) was 46 years old, (2) held an M.D. degree and a Ph. D. degree in Physics, (3) had served in various research positions for 18 years, including part-time research for 8½ years while completing the requirements for a doctor's thesis in microbiology and a Ph. D. degree in physics, and (4) had participated in or was the principal investigator on 19 original investigations and theoretical treatises. The application requested basic salary support of $18,000 a year with annual increases of $800. The Chairman of his department at the sponsoring institution advised in the application that this awardee should be considered an experienced investigator quite capable of carrying on his own independent research. Shortly after the renewal of his development award, this awardee was promoted to the rank of professor of physiology.

"The files pertaining to the second awardee showed that at the time his application for a 5-year extension of his development award was reviewed by NIH, the awardee (1) was 52 years old, (2) had held a Ph. D. degree in biochemistry for about 25 years, (3) had been a full professor for about 6 years, (4) had participated

in more than 40 listed publications on original investigations and theoretical treatises, (5) was the principal investigator under an NIH research project which had received grants totaling more than $173,000 through fiscal year 1965, and (6) was the senior member, next to the Chairman, of the university's Biochemistry Department. The basic salary support applied for was $25,000 a year.

"The third awardee's application for a research career development award provided for basic salary support of $20,000 a year. The application shows that he (1) was 33 years old and held an M.D. degree and an M.S. degree in biochemistry, (2) had held the position of clinical associate at NIH for 2 years, (4) had been a senior investigator at NIH for 5½ years, and (5) for 6 months had been Director of the Laboratory of Molecular Biology, Professor of Biochemistry, and Associate Professor of Medicine at the sponsoring institution. In addition, the awardee had participated in 30 original research investigations. This awardee advised us that he though that he had advanced beyond the concept of the research career development award.

"We believe that the circumstances pertaining to the three career development awards discussed above raise some doubts as to whether these awards were proper. All three of the awardees appeared to be experienced investigators and were members of the faculty at their respective institutions. In each case the application submitted by the institution indicated that the awardee had reached the stage in his scientific development that would qualify him as a candidate for a career award. Since the career award segment of the program was curtailed prior to the approval of these three applications, we believe that it is questionable whether the three investigators should have been supported under this segment of the program. In our opinion the facts relating to these three individuals and statements made to the Congress indicate that funds awarded to the institutions in the form of the institutional general research and/or training grants rather than Research Career Program funds could have been utilized to pay their salaries."

General Accounting Office stated that they did not request formal comments of the Department of Health, Education, and Welfare or of the institutions visited during the review, on the information cited above. Accordingly, to that extent, the conclusions and opinions expressed should be recognized as tentative.

Appendix H

Part 1—Proposed Reorganization of the Food and Drug Administration, May 4, 1966

(Approved by Secretary Gardner on June 17, 1966)

Approval is requested for changes to the FDA organization as described in this proposal. The format of this proposal is presented in accordance with the DHEW General Administration Manual, Chapter 8–60, and is divided into the following subject areas:

A. Proposed Changes and Circumstances.
B. Changes in Functions and Assignments.
C. Justification in Terms of Sound Organization Criteria.
D. Impact on Other Organizations.
E. Budgetary and Staffing Implications.

A. Proposed Changes and Circumstances

1. Establishment of an Associate Commissioner for Compliance

The functional responsibilities of FDA are divided into two broad areas—science and compliance. Responsibility for these two areas has been diffused throughout FDA with no central coordination other than that which could be provided by the Commissioner himself.

Two Associate Commissioners—one for Science and one for Compliance—will provide the high level of attention and coordination required for these two major functional areas. The position of Associate Commissioner for Science has been approved by the Secretary. Establishment of the Associate Commissioner for Compliance will complete the balanced organizational FDA structure at this level. The Associate Commissioner for Compliance will be responsible for advising the Commissioner concerning all aspects of regulatory and voluntary compliance in FDA and for ensuring uniformity of compliance action in FDA organizations.

The Associate Commissioner for Compliance will also be assigned responsibility for directing and coordinating the regulation-making activities of FDA. Since FDA regulations provide the public and industry with direction for compliance with public laws, it is essential that responsibility for directing their preparation be assigned to the organization having responsibility for the overall compliance function of the Agency. Functions currently assigned to the Assistant Commissioner for Regulations will be assigned to the Associate Commissioner for Compliance and the position of Assistant Commissioner for Regulations will be abolished.

Emergency preparedness and civil defense functions are currently assigned to the Office of Emergency Preparedness. These responsibilities will be assigned to the Associate Commissioner for Compliance where they can be given high-level Agency-wide consideration. Transfer of emergency preparedness and civil defense functions from the Office of Emergency Preparedness will permit abolishment of that office, since the remaining security functions (both physical and personnel) can logically be reassigned to the Assistant Commissioner for Administration.

Establishment of the two Associate Commissioners will eliminate the requirement for the Assistant Commissioner for Operations. That office will be abolished since the day-to-day operations, decisions and problems can be adequately handled by the two Associate Commissioners. The safety program will be assigned to the Associate Commissioner for Science because the primary emphasis of the safety program concerns safe laboratory operations.

2. Establishment of an Assistant Commissioner for Education and Information

In recent years the Food and Drug Administration has frequently suffered from unfavorable publicity at the hands of mass news media. Although some of this

publicity may have been justified, much of the unfavorable publicity as distorted and the Agency reputation suffered as a result of insufficient explanation by the Agency. Such unfavorable publicity has undoubtedly seriously detracted from FDA recruiting efforts and the overall execution of programs.

The position of Assistant to the Commissioner for Education and Information was recently established. After several months of experience we find that we must consolidate, at a high level, FDA activities which are specifically concerned with presenting factual information to the press and public.

The proposed Assistant Commissioner for Education and Information will conduct a public information program that will create a positive and favorable atmosphere for FDA regulatory programs. He will assure that proper emphasis is given to newsworthy occurrences and that distortions do not occur as a result of insufficient Agency explanation. As the principal advisor to the Commissioner on public information and education, he will act as the Agency focal point for dissemination of news concerning FDA and will maintain contact with public information media.

In addition to the functions noted above, this office will concentrate on public information regarding protective measures and on the role of FDA in the total national health effort. Also, long-range plans will be developed for the education of consumers. Efforts will be made to build public understanding of FDA through such means as incorporating FDA information in educational materials, such as textbooks, and in the curricula of grade schools and universities. Contact with the public on a continuing basis will be maintained by responding to the many public inquiries received by FDA.

The proposed Assistant Commissioner for Education and Information will include the functions of and abolish the position of Assistant to the Commissioner for Education and Information and the Office of Public Information. It will also include the editorial, visual services, and public inquiries functions currently located in the Bureau of Education and Voluntary Compliance.

3. Transfer of Advisory Opinions Functions from Bureau of Education and Voluntary Compliance to Bureau of Regulatory Compliance

The Division of Case Supervision in the Bureau of Regulatory Compliance is responsible for reviewing legal actions for compliance with policy, establishing guidelines for initiation of legal actions, and development of enforcement policies. Development and issuance of advisory opinions, primarily to guide and assist the regulated industry, should be a responsibility of the same organization which provides this guidance and direction for FDA personnel. In addition to being impractical, there is potential for conflicting decisions when one organization of FDA advises industry while another develops FDA guidelines for action on the same subject matter. Responsibility for issuing advisory opinions in drug, food, device and cosmetic areas will be transferred to the Division of Case Supervision Bureau of Regulatory Compliance, from the Division of Industry Advice, Bureau of Education and Voluntary Compliance.

4. Establishment of an Office of Policy Management

The Food and Drug Administration has on file trade secrets and other privileged information submitted by industry in compliance with regulatory requirements. The volume of this material is constantly increasing as a result of additional legislation and more aggressive program execution. The possibility of intentional or unintentional disclosure of privileged information is a potential problem since the files containing this material are constantly in use in many segments of FDA. There is a general awareness of the need for tight security, but responsibility in this area is diffused throughout the Agency. At present, there is no single office in FDA responsible for formulating Agency-wide security measures to prevent disclosure of such privileged information.

The proposed Office of Policy Management would be responsible for formulating Agency-wide security measures and for investigating and recommending action concerning security problems, including security of trade secrets. This office would also advise the Commissioner on Agency policy concerning the closely related matter of conflict of interest.

5. Establishment of an Office of International Affairs

The international aspects of FDA program administration are becoming increasingly important. Recent commitments by the United States in the World Health Organization to participate in the development and analysis of adverse reaction statistics on an international basis is an example of the growing role of FDA in international affairs. Among programs under consideration is the

preinspection of foods for importation before shipment and the inspection of the industries manufacturing goods for importation.

Although various FDA organizations are currently involved in maintaining liaison with international organizations, no single office has overall Agency responsibility for coordinating these efforts. Effective leadership is needed to foster multilateral interest and cooperation on programs and problems concerning foods, drugs, cosmetics, and hazardous substances which are subject to importation into the United States. Establishment of this office should substantially further Agency efforts toward voluntary compliance with FDA regulations in other countries.

6. Redesignation of the Office of Assistant Commissioner for Planning to include Evaluation

Separation of legislative liaison functions from the Assistant Commissioner for Planning to the proposed Office of Legislative Services is discussed elsewhere. A second proposed change is to add Agency-wide program evaluation functions to the Assistant Commissioner for Planning and to change the name of that office to the Assistant Commissioner for Planning and Evaluation.

Assignment of program evaluation responsibility to this office is in recognition of the need for evaluation of program accomplishments on an Agency-wide basis. Program evaluation is currently carried out to a limited extent at various levels throughout FDA, with virtually no coordination of this effort on an Agency-wide basis. The organization which is assigned responsibility for coordinating the development of Agency objectives is the logical organization to assume responsibility for evaluating accomplishment of those objectives.

7. Designation of an Office of Legislative Services

A Legislative Services Staff was recently established to separate and clearly identify legislative liaison functions in FDA and to ensure that they are constantly responsive to the Commissioner's decisions and policy. The proposed reorganization gives office status to this important responsibility.

B. Changes in Functions and Assignments

The following changes are included in this proposal:

Exhibit 1, Present Organization Chart, Office of the Commissioner, FDA
Exhibit 2, Proposed Organization Chart, Office of the Commissioner, FDA

1. Establishment of an Office of Policy Management

This office will provide a central point where all Agency policy and efforts concerning FDA security, conflict of interest, and related matters can be coordinated and controlled. The function of FDA Security Representative will be assumed from the present Office of Emergency Preparedness which will be abolished. The remaining functions assigned to this office are not presently the assigned responsibility of any other organizational unit of FDA.

Exhibit 3, Proposed Functional Statement, Office of Policy Management.

2. Establishment of an Office of International Affairs

This office is being established to provide a central point for promoting and coordinating FDA participation in international affairs dealing with FDA assigned functions. The functions assigned to this office are not presently the assigned responsibility of any other organizational unit of FDA.

Exhibit 4, Proposed Functional Statement, Office of International Affairs.

3. Designation of the Legislative Services Staff as the Office of Legislative Services

This change is being made to provide proper organizational placement of the functions and staff. There will be no changes in functions or staffing.

Exhibit 5, Proposed Functional Statement, Office of Legislative Services.

4. Establishment of an Associate Commissioner for Compliance

This office is being established to centralize supervision of compliance functions at the staff level in a manner similar to the centralization of the science functions under an Associate Commissioner for Science. Involved in this organization change will be the—

a. Abolishment of the Office of the Assistant Commissioner for Regulations.
 1. Transfer of functions and staff, intact, to the Office of the Associate Commissioner for Compliance.
b. Abolishment of the Office of Emergency Preparedness.
 1. Transfer of emergency preparedness and civil defense functions to the Office of the Associate Commissioner for Compliance.

2. Transfer function of serving as FDA Security Representative to the Office of Policy Management.

3. Transfer of the physical security function to the Division of General Services, ACA.

4. Transfer of the personnel security function to the Division of Personnel Management, ACA.

c. Abolishment of the Office of the Assistant Commissioner for Operations.

1. Transfer safety function and the Safety Officer to the Office of the Associate Commissioner for Science.

2. Remaining functions are assumed by the functional roles of the new Associate Commissioner for Compliance and the previously established Associate Commissioner for Science.

Exhibit 6, Proposed Functional Statement, Office of Associate Commissioner for Compliance.

Exhibit 7, Present Functional Statements.

a. Office of Assistant Commissioner for Regulations.
b. Office of Assistant Commissioner for Operations.
c. Office of Emergency Preparedness.

5. *Establishment of an Assistant Commissioner for Education and Information*

This office is being established to provide, at staff level, a centralized information program including editorial and visual services. It will also provide long-range educational program planning. The consolidation will encompass functions now performed by the Assistant to the Commissioner for Education and Information, the Office of Public Information, and some of the functions now performed by the Bureau of Education and Voluntary Compliance. This will be accomplished by—

a. Abolishment of the Office of Public Information.

1. Transfer functions and staff, intact, to the Office of the Assistant Commissioner for Education and Information.

b. Abolishment of the Editorial Services Branch and Visual Services Branch, Bureau of Education and Voluntary Compliance.

1. Transfer functions and staff, intact, to the Office of the Assistant Commissioner for Education and Information.

c. Transfer of the public inquiries function and staff from the Division of Consumer Education, Bureau of Education and Voluntary Compliance, to the Office of the Assistant Commissioner for Education and Information.

Exhibit 8, Proposed Functional Statement, Assistant Commissioner for Education and Information.

Exhibit 9, Present Functional Statements.

a. Office of Public Information.
b. Editorial Services Branch, BEVC.
c. Visual Services Branch, BEVC.

6. *Transfer of the Advisory Opinions Functions from the Bureau of Education and Voluntary Compliance to the Bureau of Regulatory Compliance*

This transfer is being made to center the responsibility for advising industry on courses of action in the unit that decides actions to be taken on violations. This is to be accomplished by—

a. Transfer the advisory opinions functions and related staff from the Division of Industry Advice, BEVC, to the Division of Case Supervision, BRC.

b. The functions and staff thus transferred will be absorbed into the existing organization of the Division of Case Supervision, BRC. The functional statement of the Division of Case Supervision, the Office of the Bureau Director, and the Bureau of Regulatory Compliance will be modified by by adding the following functions:

1. Issues advisory opinions resulting from specific requests from industry, trade associations, and other government agencies and officials.

2. Selects and furnishes policy interpretation and precedent material for reference use throughout FDA.

7. *Revision of organization and functional statement of the Bureau of Education and Voluntary Compliance*

The reorganization of the Bureau is necessary because of the abolishment of several branches in the Bureau and the transfer of functions from the Bureau. (See paragraphs 5 and 6 above for specific actions).

Exhibit 10, Proposed Organization Chart, Mission and Functional Statements, BEVC.
a. Proposed Mission Statement, BEVC.
b. Proposed Organization Chart, BEVC
c. Proposed Functional Statements, BEVC.
Exhibit 11, Present Organization and Functional Statements, BEVC.
a. Present Organization, BEVC.
b. Present Functional Statement, BEVC.
c. Present Functional Statement, Division of Industry Advice, BEVC.
d. Present Functional Statement, Divsion of Consumer Education, BEVC.

8. Redesignation of the Assistant Commissioner for Planning as Assistant Commissioner for Planning and Evaluation

The title of the Assistant Commissioner is being changed to indicate the addition of the function of evaluating Agency progress in attaining program goals. No changes in organization or staffing are contemplated.

Exhibit 12, Proposed Mission and Functional Statement, Office of Assistant Commissioner for Planning and Evaluation.
a. Proposed Mission Statement, ACP.
b. Proposed Functional Statement, ACP.

C. Justification in Terms of Sound Organization Criteria

The basic justification and rationale for the changes here proposed are contained in Section A—Proposed Changes and Circumstances. These changes are designed to improve the organizational and functional structure within FDA and should substantially aid this Agency in meeting its goals and objectives. The proposed changes for the Office of the Commissioner will result in a more logical grouping of functions at the Agency level and will give appropriate emphasis to a number of important functions. The proposed changes concerning the Bureau of Education and Voluntary Compliance are designed to strengthen the Bureau's education programs and to assign other functions performed in that Bureau to more appropriate offices.

In terms of organization principles, the proposed changes are in agreement with generally accepted organization criteria. Although they are not listed here on an item by item basis, the criteria outlined by the Department have been considered in the development of this proposal and we are satisfied that, in general, they have been met.

D. Impact on Other Organizations

The proposed changes in organization will have a favorable effect on the Agency, Department, regulated industry, and the public. The impact of increased effectiveness and efficiency will be noted as the new organizational structure becomes operational.

The Associate Commissioner for Compliance will provide needed direction and coordination for both regulatory and vountary compliance. All organizations, and the regulated industries in particular, should become increasingly aware of Agency efforts to administer strong regulatory programs and, at the same time, to bring about compliance on a voluntary basis. Realignment of compliance functions within the Bureau of Regulatory Compliance will also further FDA efforts to obtain voluntary compliance on the part of industry.

Establishment of the Office of Assistant Commissioner for Education and Information will help ensure that the public is factually informed to understand Agency objectives and actions so that they can adequately protect themselves by being better informed in the areas of foods, drugs, cosmetics and therapeutic devices. The Food and Drug Administration will be able to function in a more favorable climate if the public is adequately informed concerning Agency activities.

FDA units, as well as the Department of Health, Education, and Welfare, should benefit from the assignment of Agency-wide program evaluation responsibilities to one organization at a high level within the Agency. The Assistant Commissioner for Planning and Evaluation will coordinate Agency evaluation functions and will compare planned performance with actual performance.

The proposed Office of International Affairs will provide Agency-wide coordination for this function which is presently diffused throughout the Agency and which is becoming increasingly important. Similarly, Agency security functions

will be clearly identified and central coordination will be a responsibility of the Office of Policy Mangement.

Improved coordination with Congress should result from establishment of the Office of Legislative Services. This change identifies these important responsibilities with a specific office responsible to the Commissioner. The responsibility for day-to-day contact with Congress will be separated from the long-range planning responsibilities of the Assistant Commissioner for Planning and Evaluation.

E. Budgetary and Staffing Implications

The changes contained in this proposal will be accomplished without any additional staff requirements. In fact, it is anticipated that the proposed organization will require somewhat fewer personnel than presently budgeted, permitting the reallocation of a small number of positions to other FDA programs.

There are no major budgetary implications attendant to this reorganization proposal other than personnel costs. Since the total number of positions may be reduced somewhat, no increase in personnel cost is anticipated.

Exhibit 1.—Present Organization Chart, Office of the Commissioner, FDA

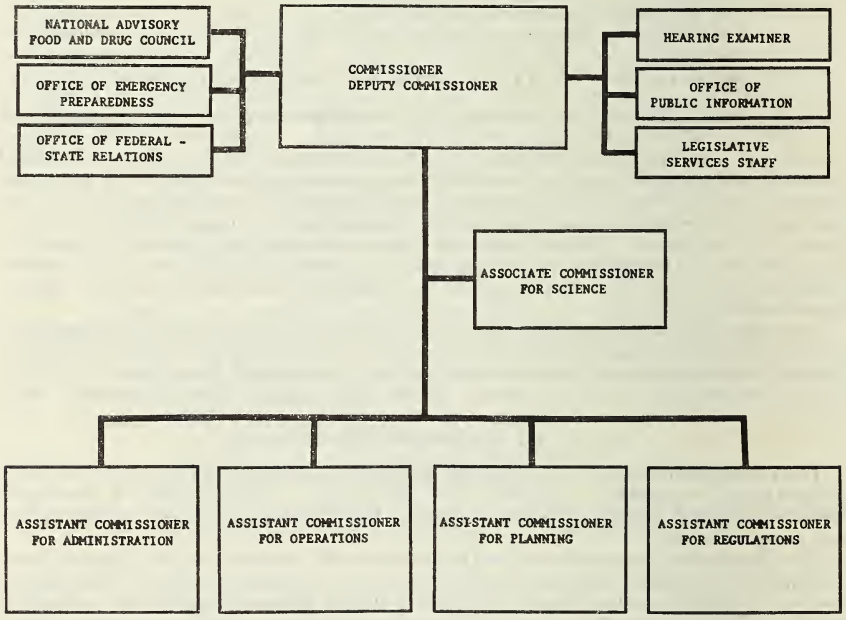


EXHIBIT 2.—PROPOSED ORGANIZATION CHART, OFFICE OF THE COMMISSIONER, FDA

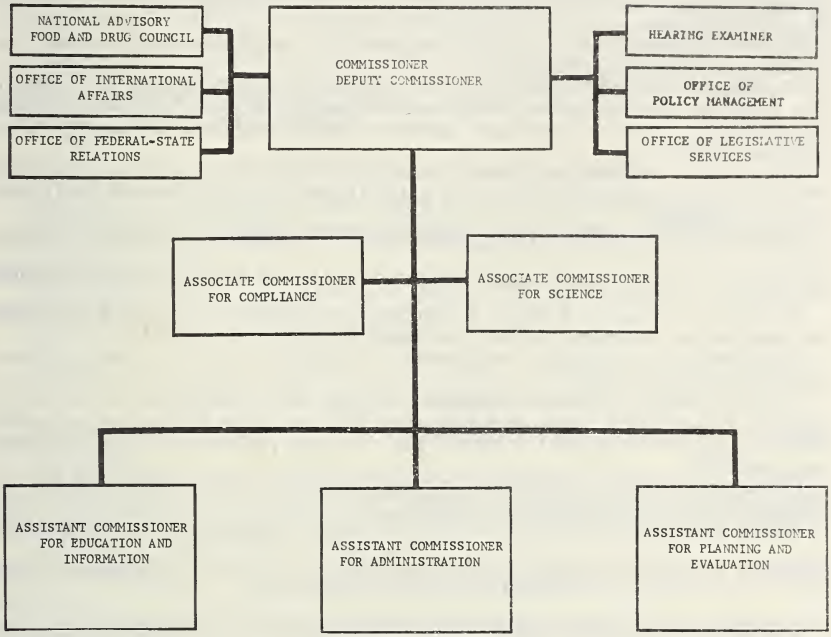


EXHIBIT 3. PROPOSED FUNCTIONAL STATEMENT, OFFICE OF POLICY MANAGEMENT

Advises the Commissioner on policy and procedures necessary for maintaining the integrity of trade secrets and other privileged information submitted by industry to the Food and Drug Administration. Formulates Agency-wide security measures to be followed to prevent disclosure of such privileged information to unauthorized sources. Investigates and recommends action concerning problems associated with security.

Serves as FDA representative and liaison with the Office of Internal Security, OS, and participates with them in developing and implementing intra-agency policy and procedures for security-related matters.

Advises the Commissioner on policy and special problems concerning conflict of interest and/or potential conflict of interest.

Establishes broad Agency-wide policy, and reviews and initiates actions as necessary to maintain a climate of confidence, on the part of regulated industry and of the general public, in the integrity of the Food and Drug Administration.

Reviews the administration of fair employment practices within the Agency and recommends corrective action as may be indicated.

EXHIBIT 4. PROPOSED FUNCTIONAL STATEMENT, OFFICE OF INTERNATIONAL AFFAIRS

Advises the Commissioner on all FDA matters having international implications.

Develops position papers on international programs as recommendations to the Commissioner. Helps to coordinate implementation of such programs.

Maintains liaison with international organizations concerned with foods, drugs, cosmetics, and/or hazardous substances such as the World Health Organization, Committee on Narcotic Drugs, and the Food and Agriculture Organization, and represents FDA at meetings of such organizations.

Represents FDA at meetings concerning international affairs when requested to do so by the Commissioner.

Assumes leadership in the fostering of multilateral interest, support, and action by other countries in administering FDA-type regulatory programs of foods, drugs, cosmetics, and hazardous substances which are subject to importation into the United States.

Fosters international cooperation on problems concerning foods, drugs, cosmetics, and hazardous substances.

Maintains constant liaison and close working relationships with the Office of the Assistant Secretary for Health and Scientific Affairs, DHEW, regarding developments, trends, programs, policies, and procedures concerning international activities.

Maintains a working relationship with other U.S. Government organizations that deal in international affairs, such as the Department of State and the Department of Defense.

Represents the Food and Drug Administration in relations with foreign visitor s

Exhibit 5. Proposed Functional Statement, Office of Legislative Services

Develops the Food and Drugs Administration position on proposed legislation or amendments to provide for new or changed programs.

Responsible for appraising congressional attitudes towards the basic enforcement program activities.

Conducts liaison with the Congress, working with committees of the Senate and the House which consider substantive food and drug legislation, to include drafting, justifications, and interpretation of laws pertaining to foods, drugs, and cosmetics.

Coordinates pertinent activities and acts as liaison with the Office of the Assistant Secretary for Legislation, DHEW.

Serves as focal point for coordination of congressional inquiries and requests.

Exhibit 6. Proposed Functional Statement, Office of Associate Commissioner for Compliance

Functions as principal advisor to the Commissioner on regulations and compliance-oriented matters which impact on policy and Agency-level decisions.

Evaluates and coordinates FDA's overall compliance effort to assure an optimum use of FDA resources (combined with other Federal, State, and local resources), a balance between voluntary and regulatory compliance, and FDA responsiveness to consumer needs.

Stimulates an awareness within the Agency of the need for prompt and positive action to secure compliance by the regulated industries.

Directs and coordinates the regulation-making activities of the Food and Drug Administration, to include procedural regulations, interpretive regulations, exempt regulations, rule-making regulations, and formal and informal regulatory policy statements. Responsible for preparation of Federal Register material.

Counsels the Commissioner on courses of action necessary to rectify major deficiencies in compliance programs as reflected in formal program evaluation reports prepared by responsibile staff officers. Determines impact on and/or need for major changes in Agency policy and direction and long-range program goals.

Operates FDA emergency preparedness and civil defense program. Coordinates FDA delegate-agency and other civil defense responsibilities, and special FDA programs designated to meet national disaster and emergency requirements. Serves as liaison between FDA and outside agencies and industry on emergency preparedness matters.

Exhibit 7. Present Functional Statements

A. OFFICE OF THE ASSISTANT COMMISSIONER FOR REGULATIONS

Directs and coordinates the regulation-making activities of the Food and Drug Administration, to include procedural regulations, interpretive regulations, exemption regulations, rule-making regulations, and formal and informal regulatory policy statements.

Responsible for the preparation of Federal Register material.

Advises the Commissioner concerning the adequacy and effectiveness of existing or proposed regulations.

Coordinates special projects on behalf of the Commissioner.

B. OFFICE OF THE ASSISTANT COMMISSIONER FOR OPERATIONS

Responsible for the overall coordination of FDA day-to-day operations, to include the implementation of special assignments directed by the Commissioner.

Serving in a staff capacity, coordinates the development of on-the-spot decisions in response to day-to-day problems arising out of operating programs.

Serves as a focal point to which operating bureaus can turn in cases where current policy does not coincide with the circumstances at hand.

Directs the FDA safety program.

C. OFFICE OF EMERGENCY PREPAREDNESS

Operates FDA emergency preparedness and civil defense program.

Coordinates FDA delegate-agency and other civil defense responsibilities.

Serves as liaison between FDA and outside agencies and industry on emergency preparedness matters.

Coordinates special FDA programs designed to meet national disasters and emergencies.

Serves as FDA security representative.

EXHIBIT 8. PROPOSED FUNCTIONAL STATEMENT, OFFICE OF THE ASSISTANT COMMISSIONER FOR EDUCATION AND INFORMATION

Acts as principal advisor to the Commissioner concerning public information and education.

Plans, coordinates, and participates in a comprehensive public information program for the Agency and acts as a focal point for dissemination of news concerning FDA activities; maintains contacts with the press and other public information media for this purpose.

Gives proper emphasis to newsworthy occurrences and assures that distortions of FDA intentions do not occur as a result of insufficient explanation by the Agency.

Conducts a public information program that will create a positive atmosphere for FDA regulatory programs and will be conducive to the FDA personnel recruitment effort.

Maintains contact with key individuals and organizations in the field of education and educational materials in order to interest them in the role of FDA as an item of educational importance.

Reviews long-range plans and sets long-range goals for consumer educational programs.

Reviews all speeches and other informational material prepared for public presentation to assure that they are in agreement with the latest FDA and Department policies.

Provides editorial, design, and graphic art services to FDA headquarters activities.

Answers public inquiries and corresponds with the public on topics of consumer interest.

EXHIBIT 9. PRESENT FUNCTIONAL STATEMENTS

A. OFFICE OF PUBLIC INFORMATION

Advises the Commissioner on Public relations, press and related matters involving communication with the public. Serves as the focal point for releases of information customarily disseminated through the medium of the press, television, radio, magazines, and various related publications.

The Office of Public Information is comprised of specialists in the different forms and media of communication who prepare press releases, statements, speeches, fact sheets, scripts, etc.; answer press and public inquiries, and operate the Public Information Center (a document and inquiry service) for the Food and Drug Administration.

Under the supervision of the Director of Public Information, FDA staff members of the Office of Public Information maintain contact with media of public communications and with organizations and groups who carry on information and communication activities related to the objectives of the Federal Food, Drug, and Cosmetic Act. They—

(1) Assist FDA publishers, editors, writers, and reporters in their covering and reporting of FDA activities.

(2) Keep the Commissioner informed regarding developments in the area of public information.

(3) Advise the Commissioner and key officials, including the Office of Public Information, DHEW, regarding public information developments, programs, and problems.

(4) Prepare speeches, statements, and material for use by the Commissioner or transmittal to the Office of Public Information, DHEW, for use by the Secretary or others.

(5) Assist the Director in carrying out his functions as principal information officer of the Food and Drug Administration.

Because both the Office of Public Information and the Bureau of Education and Voluntary Compliance have an interest in public informational materials and related matters, it is necessary that both units work closely together in dealing with various informational media.

The principal difference between the mission of the two organizations is that the Office of Public Information is primarily responsible for staff assistance to the Commissioner in the area of public information and for dealing with the press and other news media on a spontaneous basis.

The Bureau of Education and Voluntary Compliance, on the other hand, is responsible for establishing and maintaining substantive operating programs having to do with education, information and the promotion of voluntary compliance.

The execution of such voluntary compliance programs often depends on the effective utilization of various informational and news media.

B. EDITORIAL SERVICES BRANCH, BEVC

Provides the basic services involved in the planning, writing, securing necessary reviews and clearances, and final editing and publishing of the Annual Report, Monthly Report of Enforcement and Compliance, and Food and Drug Review.

Edits and publishes Notices of Judgment as required by law.

Makes continuing review and necessary editorial revisions of all laws enforced by FDA as amendments occur; and of the General Regulations and Food Standards Regulations under the Federal Food, Drug, and Cosmetic Act.

Provides services for the Divisions of Consumer Education and Industry Advice in the editing and copy preparation of pamphlets, articles, and other written materials for mimeograph or immediate production by offset or letterpress of publications with established format; or for submittal to the Visual Services Branch for deisgn and layout and illustration as necessary.

Arranges with the Division of General Services, ACA for final production and necessary liaison with GPO and ordering adequate stocks of BEVC materials.

Establishes and maintains necessary mailing lists for reaching consumer, industry, and professional groups with FDA's educational material.

C. VISUAL SERVICES BRANCH, BEVC

Plans, designs, and produces visual materials in support of FDA programs.

Develops visual aspects of projects initiated by the Divisions of Industry Advice and Consumer Education.

Provides visual services for other FDA units.

Designs and illustrates printed materials for which no format has been established, and provides layouts for production by Editorial Services Branch.

Designs, illustrates, and produces visual presentations (such as filmstrips and TV packages) in collaboration with program officers.

Executes an exhibit program, including the FDA educational museum and specimen collection, and designs and produces exhibits with conceptual and textual aid from program officers.

Maintains current files of still photos, filmstrips and movies, and services external and internal requests for these materials.

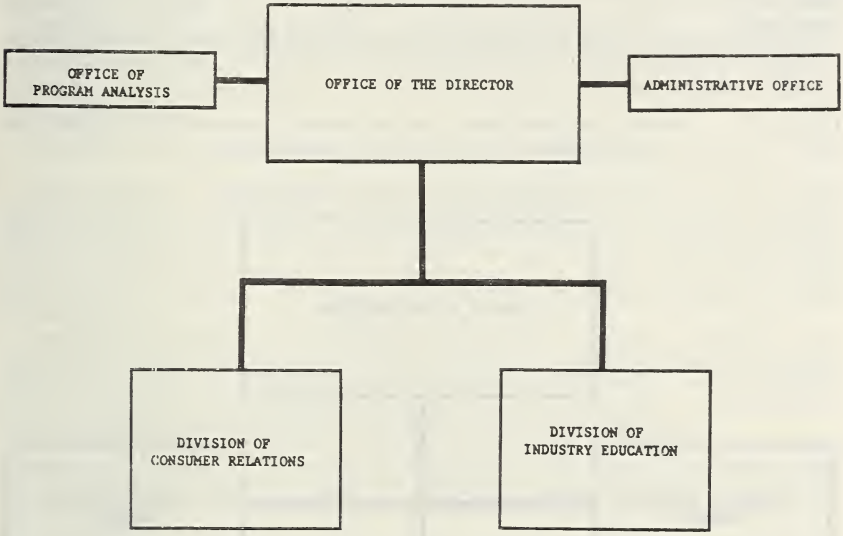
Exhibit 10. Proposed Organization Chart, Mission and Functional Statements, Bureau of Education and Voluntary Compliance

A. PROPOSED MISSION STATEMENT, BEVC

The mission of the Bureau of Education and Voluntary Compliance of the Food and Drug Administration is to effectively educate the public to avoid health hazards, frauds, and quackery, and to give industry the greatest possible opportunity to comply with FDA regulations through a cooperative program of education. This mission directly supports the overall FDA mission of protection of

the public. In addition to educating the public to protect itself, the mission emphasizes the role of FDA in providing industry with the facts and techniques to produce products that meet the Agency's regulatory standards. An effective program in meeting this mission would minimize the need for regulatory actions against industry, particularly where the intention of industry is to wholly comply with FDA regulations and standards.

B. PROPOSED ORGANIZATION CHART, BEVC



C. PROPOSED FUNCTIONAL STATEMENT, BEVC

Office of the Director

Conducts a broad program of promoting voluntary compliance and cooperation between the public, the regulated industries, and the Food and Drug Administration through educational and informational activities.

Conducts programs to effectively inform specific segments of the population to avoid abuse and misuse of drugs; avoid health hazards, frauds, and quackery; and to use drugs safely and effectively.

Conducts programs aimed at effectively providing industry with facts and techniques that will give industry the greatest opportunity to comply with FDA regulations and standards. Decides areas of emphasis and techniques to be used for such programs.

Determines consumer attitudes, interests, and values; industry trends and attitudes; and program effectiveness through the use of special surveys.

Division of Consumer Relations

Conducts educational and informational programs to assist consumers in deriving the most benefit from the Federal Food, Drug, and Cosmetic Act and related laws. Organizes and conducts meetings, workshops, and seminars for providing consumer information directed to specific population groups, such as low income, senior citizens, youth, and other representative consumer organizations.

Initiates plans and prepares informational material in support of areas of responsibility. Initiates plans for movies, radio and TV spots, filmstrips, exhibits, and other audio-visual materials as required to support meetings, workshops, and seminars. Designs, plans, and recommends consumer surveys as required.

Implements programs in schools, colleges, and universities relevant to Federal Food, Drug, and Cosmetic Act.

Makes long-range plans in the areas of the division's responsibilities.

Division of Industry Education

Conducts programs to encourage and promote industry self-improvements and self-regulation.

Assures understanding of FDA regulations and policies by the regulated industries. Prepares and distributes informational material to explain FDA's laws, regulations, and policies.

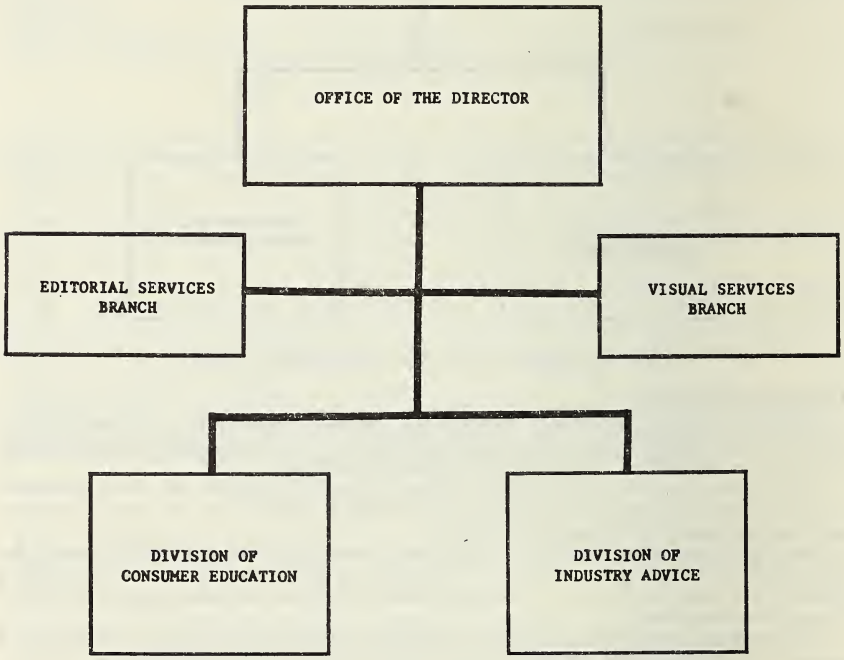
Organizes and conducts meetings, workshops, and seminars for discussion of new laws or amendments, proposed regulations, and for providing industry with facts and techniques to produce products that meet the agency's regulatory standards.

Initiates plans for visual materials in support of division's areas of responsibility.

Makes long-range plans for carrying out an effective industry voluntary compliance program.

EXHIBIT 11.—PRESENT ORGANIZATION AND FUNCTIONAL STATEMENTS, BUREAU OF EDUCATION AND VOLUNTARY COMPLIANCE

A. PRESENT ORGANIZATION CHART, BEVC



B. PRESENT FUNCTIONAL STATEMENT, BEVC

Responsible for broad program to promote voluntary compliance and cooperation between the public, the regulated industries, and the FDA through educational and informational activities.

Initiates programs aimed at educating and informing the consuming public, and providing the industries with FDA's informal opinions regarding the law, regulations, procedures, and contemplated practices to further voluntary compliance by the regulated industries.

Conducts special surveys and studies to determine consumer attitudes, interests, and values and industry trends and attitudes.

Responsible for the development and utilization of modern educational and informational techniques.

C. PRESENT FUNCTIONAL STATEMENT, DIVISION OF INDUSTRY ADVICE, BEVC

Conducts programs to encourage and promote industry self-improvement and self-regulation.

Assures understanding of FDA regulations and policies by the regulated industries.

Issues advisory opinions resulting from specific requests from industry.

Participates in the formulation of enforcement policy and programs.

Prepares and distributes informational material to explain FDA's laws, regulations, and policies.

Organizes and conducts meetings, workshops, and seminars for discussion of new laws or amendments, proposed regulations, and other matters of special interest to industry.

Selects and furnishes policy interpretation and precedent material for use throughout FDA.

D. PRESENT FUNCTIONAL STATEMENT, DIVISION OF CONSUMER EDUCATION, BEVC

Plans, organizes, and directs a program of consumer education to help achieve effectiveness of the Federal Food, Drug, and Cosmetic Act and related laws by assisting consumers to learn to use drugs safely and effectively; prevent accidental claims, choose health products and services wisely; avoid quackery and other frauds and cheats; participate in standards-making and other governmental processes; and otherwise to obtain all of the intended benefits from this and related laws.

Develops and utilizes all appropriate informational materials, techniques, and channels of communication to reach consumers, including those in such various population groups as students, older Americans, the socially or economically under-privileged, foreign language groups, and the physically handicapped, as well as consumer and professional organizations and their leaders.

Plans and directs a program to assure a flow of information from consumers, through the Consumer Consultants, consumer surveys and other appropriate research; to learn consumer needs and to disvover gaps in consumer protection and how to remove them; and to find out consumer attitudes about FDA policies and programs.

Exhibit 12. Proposed Mission and Functional Statement, Office of Assistant Commission For Planning and Evaluation

A. PROPOSED MISSION STATEMENT, ACP

The mission of the Assistant Commissioner for Planning and Evaluation is to provide executive leadership in the Administration of FDA long range planning and programming and to provide a mechanism for the analyses of its program accomplishments. This planning and evaluation process assists agency top management decisions on solutions to major program issues and the selection of program alternatives most likely to achieve the agency's long range objectives. This process presents a systematic array of multi-year programs against which the future year costs and returns of present day programs can be measured. The planning-programming-budgeting system of the Department provides the basis and program structure within which FDA develops its multi-year planning and programming. The system calls for an analytic effort which gives an in-depth examination of program objectives and criteria of accomplishments and thus enhances the validity of agency planning and programming. The system provides an orderly means of achieving agency-wide program continuity and coordination.

Cohesive agency-wide planning-programming activities are a vital contribution to the successful accomplishment of the FDA mission. The Office of the Assistant Commissioner for Planning and Evaluation provides a formal mechanism to help develop, integrate, review and approve planning proposals as well as to provide a means for continuous review, evaluation and feedback from operations. The application of a high level of planning and evaluation skill and having a planning-programming system paralleling that of the Departments enhances the quality and acceptability of FDA long range program plans.

B. PROPOSED FUNCTIONAL STATEMENT, ACP

Responsible for FDA long-range planning including program analysis.

Develops and participates in the administration of the FDA planning-programming-budgeting system by: assisting the Bureaus in developing long-range objectives; developing cost-benefit studies; providing staff leadership in the conduct of economic and demographic studies as a basis for forecasting trends, needs, and major problems requiring solution.

Coordinates intra and inter-agency planning-programming; provides liaison with the Department Office of Program Coordination.

Consolidates and issues FDA Five-Year plan. Evaluates program accomplishments against objectives and priorities.

Part 2—Proposed Reorganization of the Bureau of Medicine, Food and Drug Administration, July 8, 1966

(Approved by Secretary Gardner on July 11, 1966)

Approval is requested for changes to the FDA organization as described in this proposal. The format of this proposal is presented in accordance with the DHEW General Administration Manual, Chapter 8–60, and is divided into the following subject areas:

A. Proposed Changes and Circumstances.
B. Changes in Functions and Assignments.
C. Justification in Terms of Sound Organization Criteria.
D. Impact on Other Organizations.
E. Budgetary and Staffing Implications.

A. Proposed Changes and Circumstances

1. Introduction

The proposed organization for the Bureau of Medicine is structured to deal more effecitively with problems that have emerged since the last reorganization of these essential functions. The most significant change is the establishment of an Office of New Drugs so constituted as to bring a continuity of high skill levels to continuing problems and to apply the economic principle of specialization of labor to medical specialities. Continuity of skill applications is carried out through the entire structure of the Bureau. Like things are logically concentrated not only in the Office of New Drugs but also in the Office of Medical Review and Office of Drug Surveillance. Functions that existed in disparate parts of FDA but which on critical review were found to be essential to the mission of the Bureau of Medicine have been recommended for transfer to that Bureau. Administrative functions formerly dispersed within scientifically oriented activities have been vested in the Executive Office of the Bureau thus permitting concentration on scientific matters by scientists and concentration on administrative matters by administrative persons.

The term "Office" has been used for the major subdivisions of the Bureau of Medicine. This term is a variation from the usual organizational terminology used in the Food and Drug Administration. The term has been used, however, in recognition of the importance of the functions of this Bureau. The term Division is designated for the subordinate organizations within each Office. The term Branch would convey an erroneous connotation for the activities described herein as Divisions. We submit that there is ample precedent for calling the major subdivisions of a Bureau or comparable activity by the term Office. For example, there is an Office of Administration in the Office of the Secretary and also an Office of Management Policy and an Office of Internal Security. Within the Office of the Surgeon General, there is an Office of International Health and an Office of Information and Publications.

2. Abolishment of the Existing Office of Medical Director and the Divisions of the Bureau of Medicine

The changes proposed in this plan are of such scope and breadth as to necessitate the abolishment of all existing Divisional designations in the Bureau of Medicine and, in addition, the current Office of the Medical Director. As this proposal represents a fundamental regrouping and streamlining of functional relationships within the Bureau, the only practical approach has been to discard existing structures and to build anew based on our past experience and future expectations.

3. Establishment of an Office of the Director, Bureau of Medicine

The previous nomenclature used in designating this Office was Office of the Medical Director. We believe that this title tended to misrepresent the functions and duties of the job. In its stead we wish to achieve a more generally accepted title in line with Department policy. The incumbent of the top job will be the Director, Bureau of Medicine.

In addition to the immediate office of the Director, we propose to establish a number of staff offices to assist the Director and to carry out essential support functions at the Bureau level. Included among these are an office of the Executive Officer. This office is being established to provide the Bureau with strong administrative support in such areas as financial management, personnel, administrative services, and program analysis. This Office will also control documents and perform Drug Indexing as a service to the Bureau's Medical staff.

We are also recommending the establishment of our assistants to the Director to give him needed assistance in the areas of industry coordination, scientific investigations, and medical resources and liaison. These Offices will not only assist the Director, but also will perform essential supportive functions for the entire Bureau. As an example, the Assistant to the Director for Medical Resources and Liaison will, in addition to liaison functions, operate a statistical evaluation office and maintain a medical library designed to serve the Bureaus medical and scientific staff.

4. Establishment of an Office of New Drugs Containing Divisions Established Along Pharmacologic and Physiologic Lines and Designed to Attain One-Stop IND-NDA Processing

At the present time the processing of IND's and NDA's is conducted on a functional basis. IND's and NDA's are sent to separate groups of medical officers for medical review. Antibiotic drug IND's and NDA's are reviewed by a third group of medical personnel. Manufacturing procedures and controls are reviewed by personnel in Branches separate from the medical officers, and toxicological reviews are conducted in a Bureau other than the Bureau of Medicine. In reference to antibiotic drugs, the manufacturing controls and regulations functions also are performed in a Bureau other than the Bureau of Medicine.

As might be imagined, the processing described above has many disadvantages. The procedural steps are numerous and over-all processing operations are extremely complex. Administrative delays are frequent and the stop-start nature of the operations entails much review of foregoing work before each operation can be completed. FDA frequently has received adverse criticism stemming from events which, upon analysis, proved to be a result of our IND–NDA review procedures. Instead of the previous functional approach, we are recommending establishment of an Office of New Drugs which will be constituted of six Divisions. These Divisions will be organized along lines of pharmacologic and physiologic classification. Proposed titles for the six Divisions are:

Division of Cardiopulmonary and Renal Drugs.
Division of Neuropharmacological Drugs.
Division of Dental and Surgical Adjuncts.
Division of Metabolism and Endocrine Drugs.
Division of Anti-Infective Drugs.
Division of Oncology and Radiopharmaceuticals.

The proposed Divisions will be self-contained for IND–NDA reviewing. Medical Officers, Chemists, and Pharmacologists (toxicologists) will be formed into groups or teams to complete the review from all aspects at one point. NDA's subsequent to prior IND's will be reviewed within the same organization.

We believe that the proposed Office of New Drugs has many advantages over the current organization. It will simplify processing operations and increase FDA's ability to respond in a timely manner to industry proposals. Under this new structure, we believe that the Food and Drug Administration will be able to more effectively protect the health of the American public.

5. Abolishment of the Antibiotic Drug Application and Regulations Section, DAIC, Bureau of Science, and Assignment of its Functions to the Division of Anti-Infective Drugs

At the present time the review of antibiotic drug IND's and NDA's is split between two Bureaus in FDA. The Division of Antibiotic Drugs, Bureau of Medicine, reviews the applications from a medical and labeling standpoint, whereas the Antibiotic Drug Application and Regulations Section, Bureau of Science, reviews manufacturing procedures and controls and prepares regulations

concerning antibiotic drugs. This functional split has caused administrative and processing delays and has resulted in the Bureau of Science performing duties which the Bureau of Medicine performs for other classes of drugs.

We propose transferring the functions performed within the Antibiotic Drugs Application and Regulations Section along with appropriate staff to the Division of Anti-Infective Drugs, Bureau of Medicine.

This transfer would consolidate antibiotic drug processing within one Division and would assign to the Bureau of Medicine the same responsibility for these drugs that it has for other types of drugs. This proposal should substantially improve the timeliness of antibiotic drug IND-NDA processing and achieve the other advantages described for self-contained IND-NDA review organizations

6. Abolishment of the Drug Review Branch, Division of Toxicological Evaluation, Bureau of Science, and Transfer of its Functions and Staff to the Office of New Drugs, Bureau of Medicine

At the present time the Drug Review Branch, DTE, Bureau of Science, performs toxicological evaluations of IND's and NDA's submitted to the Bureau of Medicine. In order to achieve complete teams in the Office of New Drugs for the review and processing of IND's and NDA's, and also in order to reduce the processing steps involved in the review of these applications, we propose distributing the functions and staff of this Branch (who are for the most part Pharmacologists) to the Divisions of the Office of New Drugs.

7. Establishment of an Office of Drug Surveillance

Two of the most important functions performed by the Bureau of Medicine are the surveillance of drugs on the market for adverse reactions and the review of supplements to change or modify approved drugs. At the present time, branches engaged in these and related activities are situated in several Divisions within the Bureau with no common direction below the Bureau level. As a consequence, these closely related and critical activities have lacked the unification and close coordination which we believe they must have to carry out an effective program of health protection.

We are proposing that all drug surveillance, epidemiology, and supplement review responsibilities be consolidated and assigned to an Office of Drug Surveillance devoted exclusively to these functions.

The Office of Drug Surveillance will contain three Divisions. The Division of Supplement Review will review and appraise proposed modifications to drugs on the market and in so doing will provide a review and check of the original IND and/or NDA approval.

A Division of Drug Monitoring will be established to operate the adverse reaction reporting system and to initiate actions necessary as a result of detected adverse reactions. This Division will be engaged in developing the adverse reaction reporting base and in evaluating reports received through the system and in implementing changes as necessary.

The third proposed Division for the Office of Drug Surveillance will be the Division of Epidemiology. This Division will have responsibility for carrying out the hazardous substances responsibilities of the Bureau and for conducting clinical studies based on hospital record keeping systems.

8. Establishment of an Office of Medical Review

The proposed Office of Medical Review will be assigned the regulatory responsibilities of the Bureau of Medicine. This Office will be responsible for offering expert advice and testimony regarding fraudulent claims, proper advertising, marketing and distribution of drugs, and drug adulteration. In addition, this Office will carry out the Bureau's drug abuse responsibilities and will work closely with the Post Office Department regarding promotional materials, drugs, and devices sold or sent through the mails. The Office of Medical Review will also be responsible for developing medical facts and opinions to establish medical policy with respect to therapeutic devices and appliances having medical claims.

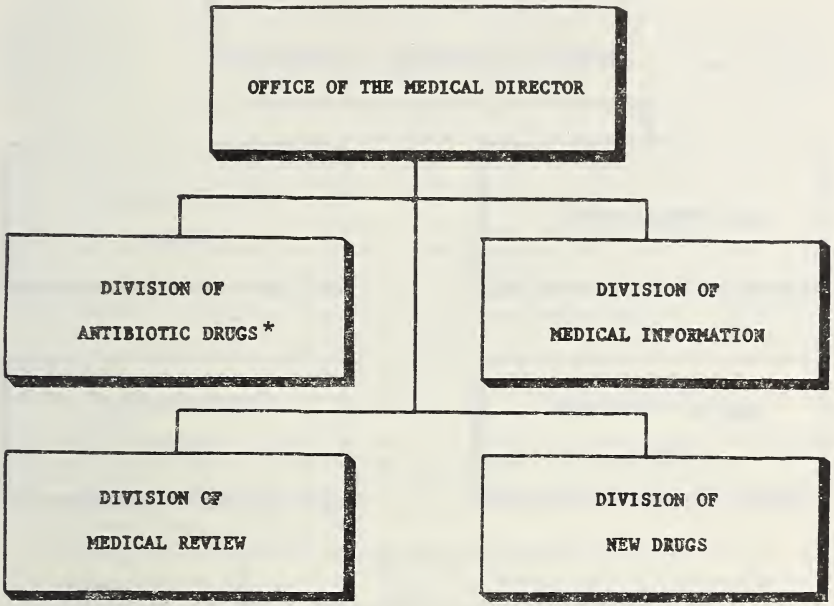
The Office of Medical Review will consist of the Office of the Director, within which there will be a Drug Abuse Coordination Staff, and the following three Divisions:

Division of Case Review.
Division of Medical Advertising.
Division of Medical Devices.

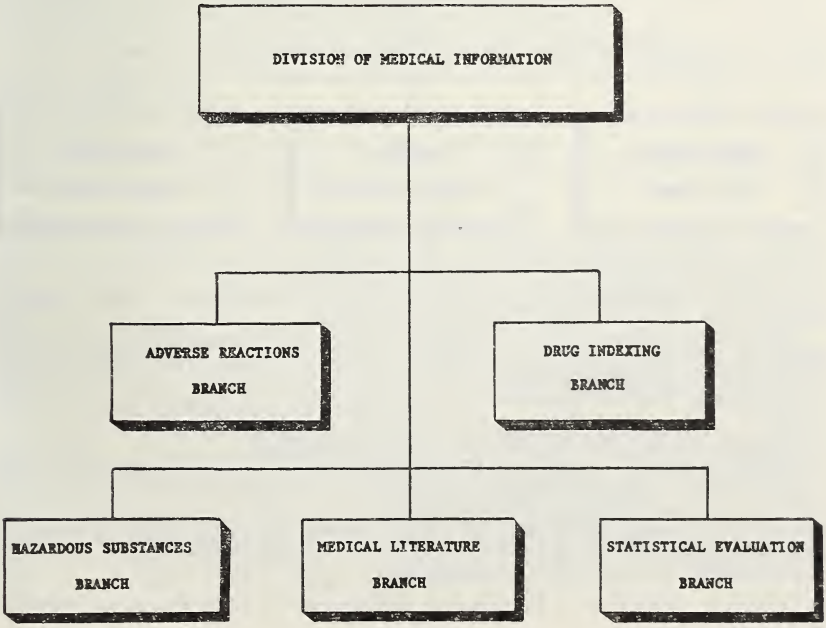
B. Changes in Functions and Assignments

Exhibit 1.—Present organizational structure and functional statements

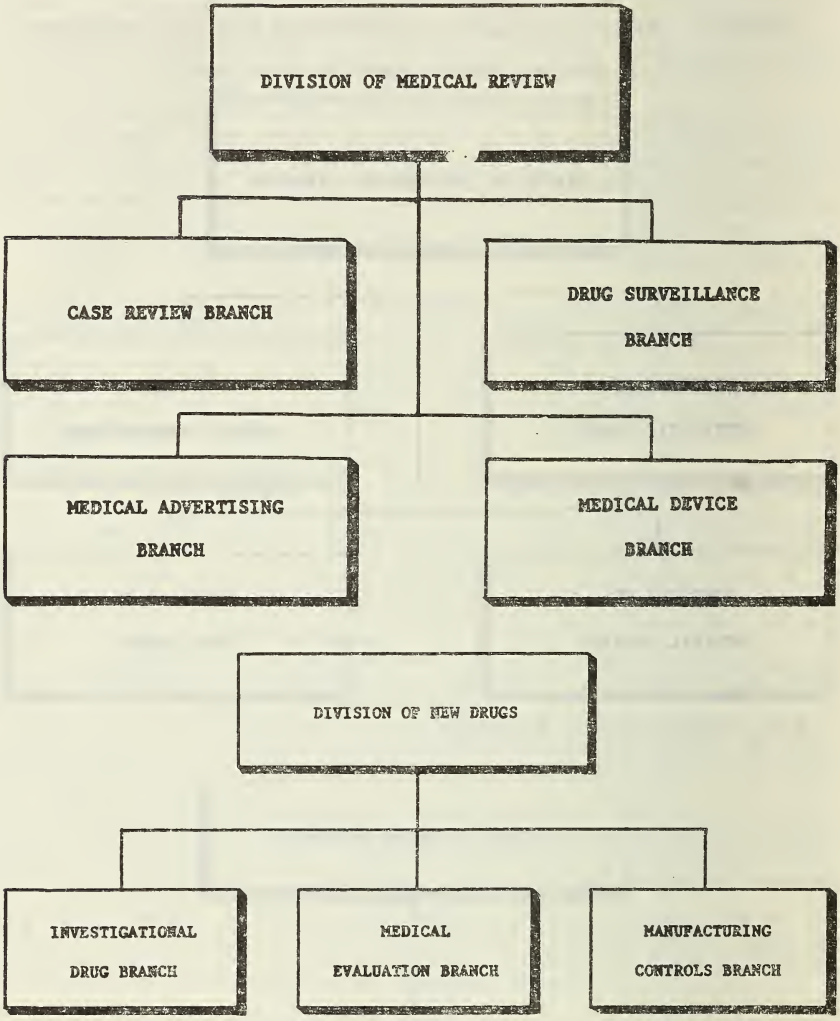
a. Present Organizational Structure, BM



* This division has no branches.



a. Present organizational structure, BM—Continued



b. Present Functional Statement, Bureau of Medicine

Develops medical policy of the Food and Drug Administration with respect to efficacy and safety for man of drugs and devices.

Establishes medical policy and furnishes the Commissioner with medical evaluation of substances found, or proposed for use, in foods, drugs, cosmetics, and hazardous household substances.

Coordinates and evaluates New Drug Applications and claims for investigational drugs.

Operates an adverse drug reaction reporting program.

Conducts through contract, a program of clinical studies of drugs and devices.

Coordinates medical aspects of FDA's inspectional and investigational programs, new drug hearings, and court cases.

Determines those drugs having a potential for abuse; develops recommendations and explanatory data for review by committees established to advise the Commissioner in this area of responsibility.

Analyzes data on drugs subject to abuse and makes appropriate recommendations for action by FDA.

In response to BDAC requirements, conducts studies on the medical aspects of drug abuse control.

c. Present Functional Statement, Office of the Medical Director, BM

The Medical Director, supported by the Deputy Medical Director, is responsible for over-all management of the Bureau and the accomplishment of its assigned mission. These officials are assisted by the Bureau's Division Directors and staff officers in the Office of the Medical Director. In the absence of the Medical Director, the Deputy Medical Director serves as Acting Medical Director.

d. Present Functional Statement, Assistant for Drug Coordination, BM

Develops proposed medical policy of the Food and Drug Administration as to whether articles are to be considered as new drugs and require the submission of New Drug Applications.

Represents the Bureau of Medicine in discussions with members of industry and others involved in the development, manufacture, and distribution of drugs, advising them personally and through correspondence of the requirements and application of the new drug regulations to particular products, and answering inquiries resulting from the announcement of proposed changes in the regulations.

Advises industry as to the status of pending New Drug Applications; in this connection consults with Division Directors and others engaged in the evaluation of New Drug Applications, their supplements, and related documents.

Serves as the liaison between the divisions of the Bureau of Medicine and the drug industry.

Coordinates, with full authority from the Medical Director, the professional efforts of the divisions, particularly as they involve the passage of drugs through the investigational phase, medical evaluation phase, and into the follow-up period.

Determines feasibility of and plans for and directs Food and Drug Administration District Medical Officer staff.

e. Present Functional Statement, Assistant for Medical Resources and Liaison, BM

Maintains effective liaison of the Bureau of Medicine with medical societies and the scientific community, both government and nongovernment.

Reviews and determines desirability of participation of staff members at professional meetings and seminars.

Develops and coordinates ad-hoc, continuing, and full-time consultant structure and staff, including eminent physicians and other scientists.

Designates and assists executive secretaries of ad-hoc committees and panels.

Supervises clinical studies and other research activities originating in the Bureau of Medicine and determines their soundness in relation to objectives and over-all program goals.

Advises Bureau staff members as to established criteria for clinical research and utilization of clinical pharmacological laboratory.

Advises and assists the Medical Director in all areas of medical liaison and research of interest to the Bureau of Medicine.

f. Present Functional Statement, Executive Officer, BM

Serves as consultant and advisor to the Medical Director, Deputy Medical Director, Division Directors and others in the Bureau of Medicine in areas of program planning, control, review, evaluation, and other aspects of program and administrative management essential to the effective execution of Bureau of Medicine functions.

Under the general direction of the Medical Director with respect to major policy decisions, and with the authority of the Medical Director, plans and manages new programs and directs conformance of all Bureau of Medicine operations with Bureau of Medicine and FDA policies.

Participates with the Medical Director and other Bureau officials in the development of the medical administrative policy and programs. Develops necessary regulations and drafts or reviews legislation with respect to drugs and devices and evaluates these in respect to policy and technical content.

Coordinates with the Office of the Assistant Commissioner for Administration in directing Bureau activities in the areas of personnel management, budget and finance, management systems and general services to assure that the appropriate support is available to the Bureau of Medicine.

Maintains a central document control operation for the Bureau of Medicine.

g. Present Functional Statement, Division of Antibiotic Drugs, BM

Determines whether the scientific evidence establishes the safety and efficacy of antibiotic drugs, and provides the Division of Antibiotics and Insulin Certification of the Bureau of Science with medical expertise and support for the formulation and execution of the certification and enforcement programs of the Food and Drug Administration with respect to antibiotic drugs.

Determines whether clinical trials of new antibiotic drugs on man are soundly conceived and are supported by prior animal testing and other controls adequately to justify the tests on man.

Determines whether applications by manufacturers for permission to market new antibiotic drugs for general use should be approved on the basis of an evaluation of the evidence of safety and effectiveness.

Maintains continuing surveillance of the labeling, advertising, clinical experience, and reports of adverse reactions attributed to all antibiotic drugs which have been released for distribution, and determines whether they show a need for revised labeling or recall of the drug from the market.

h. Present Functional Statement, Division of Medical Information, BM

Serves as a focal point within the Bureau of Medicine for the collection, evaluation, storage, retrieval and dissemination of information necessary to support programs and activities of the Bureau of Medicine.

Extracts pertinent information contained in industry proposals and incorporates it in the Bureau's information handling programs and procedures (Actual substantive processing of such documents is the responsibility of the Division of New Drugs, the Division of Medical Review and other operating units of the Bureau of Medicine).

Reviews reports of adverse reactions to drugs and other substances and evaluates to determine whether such reports should be included in the Bureau's information handling programs and the extent to which they should be disseminated to other points within the Bureau and outside.

Develops sufficient medical expertise to provide advice and opinions to other units of the Bureau concerning toxicity and hazards of chemicals used in household products, cosmetics, pesticides, and additives.

Provides basic library, research, reference, and medical literature abstracting services for other units of the Bureau.

Operates and maintains appropriate subsystems and files required to carry out the Bureau of Medicine's share of the agency-wide science information handling program now under development; represents the Bureau in developing such subsystems and files within the Bureau of Medicine and serves as a focal point for interface with the General FDA-wide system.

i. Present Functional Statement, Division of Medical Review, BM

Determines whether drugs and devices are adulterated or misbranded with respect to medical factors.

Maintains continuing surveillance of the labeling, advertising, clinical experience, and reports of adverse reactions attributed to drugs which have been released for distribution and determines whether they show a need for revised labeling or recall of the drug from the market.

Reviews inspection reports about the manner in which an approved new drug is being marketed and distributed, and determines whether marketing and distribution of the drugs are in harmony with commitments made by the manufacturer in the New Drug Application.

Evaluates safety and efficacy data and proposed labeling in supplements to new drug applications and determines whether supplements should be approved.

Evaluates and monitors the use of therapeutic devices and appliances and conducts laboratory studies to determine the physical characteristics and truthfulness or the falsity of claims made in the labeling of such devices. Develops medical evidence, arranges for clinical investigations and the procurement of expert medical witnesses, and collaborates with the Bureau of Regulatory Compliance and the Bureau of Education and Voluntary Compliance providing medical support in new drug hearing and court cases.

Furnishes medical support to the Post Office in enforcing the Post Office Fraud Law through the Post Office Collaborative Officer.

j. Present Functional Statement, Division of New Drugs, BM

Determines whether clinical trials of new drugs on man are soundly conceived and are supported by prior animal testing and other controls adequately to justify the tests on man.

Determines whether applications by maufacturers for permission to market new drugs for general use should be approved on the basis of an evaluation of the evidence of safety and effectiveness.

In doing this, evaluates the truthfulness of claims for safety and effectiveness, and the adequacy of directions for uses, and warnings against misuses, appearing in proposed labeling; the adequacy of animal, clinical, and chemical tests performed on the new drug and the suitability of manufacturing and laboratory methods, facilities and controls exercised in factories producing new drugs.

k. Present Functional Statement, Division of Antibiotic and Insulin Certification, Bureau of Science.

Administers the antibiotic and insulin certification programs involving:

(1) Evaluation of adequacy and reliability of chemical and biological data in proposals for listing for certification antibiotic and insulin drugs and dosage forms.

(2) Development of specifications, tests and methods of assay.

(3) Formulation of judgments on the nature of various antibiotic and insulin drugs and their safety and efficacy under conditions of use.

(4) Laboratory tests and assays of samples submitted for certification, including tests for identity, composition, potency, sterility, pyrogenicity.

(5) Research programs to secure and organize new scientific information about the composition, properties, and interactions of these drugs to provide bases for improvement of analytical methods and the development of sound opinions and policies.

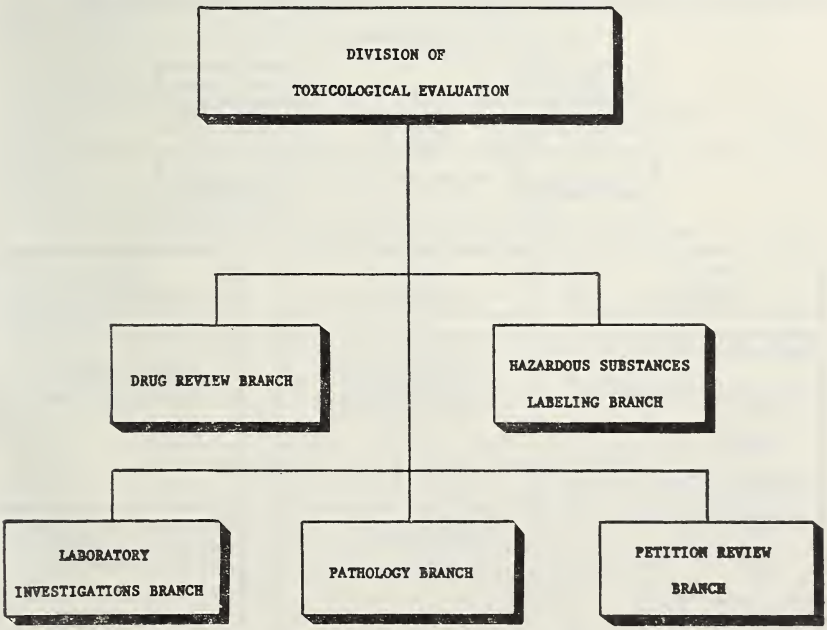
(6) Preparation and publication of appropriate regulations.

Performs examinations and tests required to support regulatory programs involving these drugs.

Serves as a repository of expertise and information concerning antibiotic and insulin drugs.

Establishes planning, reporting, and accomplishment appraisal procedures.

1. Present Organizational Structure, Division of Toxicological Evaluation, BS



m. Present Functional Statement, Division of Toxicological Evaluation, BS

Evaluates scientifically pesticide and food additive petitions with respect to to adequacy and reliability of toxicological data and tests.

Evaluates scientifically color additive petitions and proposals with respect to adequacy and reliability of toxicological data and tests.

Evaluates scientifically INDs and NDAs with respect to adequacy and reliability of pharmacological data and tests.

Evaluates scientifically labeling for hazardous substances.

Plans and conducts appropriate laboratory investigations, such as:

Acute and chronic administration studies on various classes of pesticide chemicals, food additives, drugs, colors, and hazardous substances to provide bases for evaluation of new proposals, and bases for review of existing tolerances and uses.

Investigations to check data submitted by petitioners.

Studies in application and interpretation of new procedures.

Studies to detect likelihood of potentiation of mixtures of pesticide chemicals, additives, and drugs.

Serves as a repository of expertise and information on the toxicology of pesticide chemicals, food additives, color additives, drugs and hazardous substances.

Establishes planning, reporting, and accomplishment appraisal procedures.

n. Present Functional Statement, Drug Review Branch, Division of Toxicological Evaluation, BS

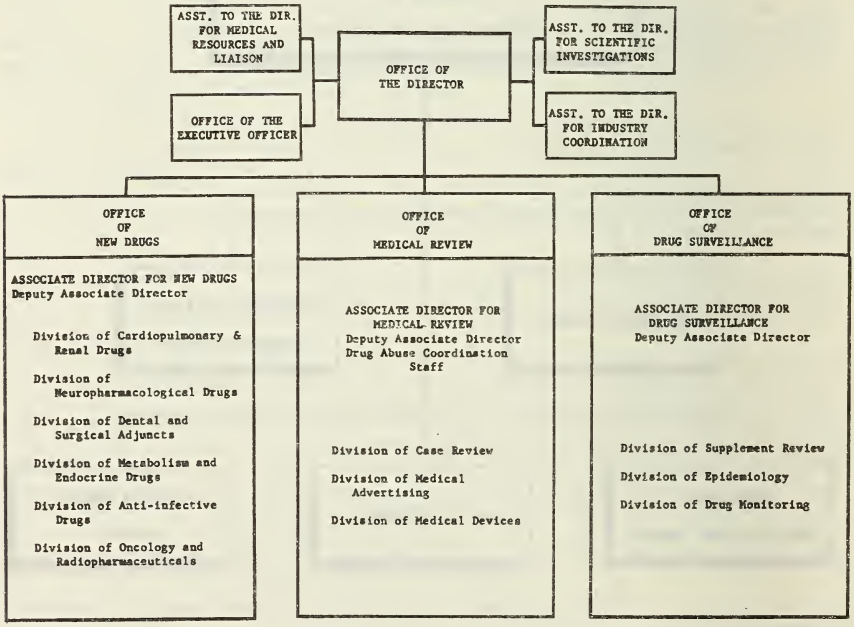
Has responsibility for the evaluation of pharmacological, toxicological, and biochemical data submitted in support of the safety and efficacy of new drugs for human use in INDs, NDAs, and Antibiotic Form 5 applications.

Acts in an advisory and consultative capacity in the area of drug efficacy and toxicity to various segments of the Food and Drug Administration, and to other governmental and industry bodies.

Conducts laboratory investigations to establish sound scientific bases for making decisions concerning the safety of drugs.

EXHIBIT 2.—Proposed organizational structure and functional statements

a. Proposed organizational structure, BM



b. Proposed Functional Statement, Bureau of Medicine

Develops medical policy of the Food and Drug Administration with respect to efficacy and safety for man of drugs and devices.

Establishes medical policy and furnishes the Commissioner with medical evaluation of substances found, or proposed for use, in foods, drugs, cosmetics, and hazardous household substances.

Coordinates and evaluates New Drug Applications and claims for investigational drugs.

Operates an adverse drug reaction reporting program.

Conducts through contract, a program of clinical studies of drugs and devices.

Coordinates medical aspects of FDA's inspectional and investigational programs, new drug hearings, and court cases.

Determines those drugs having a potential for abuse; develops recommendations and explanatory data for review by committees established to advise the Commissioner in this area of responsibility.

Analyzes data on drugs subject to abuse and makes appropriate recommendations for action by FDA.

In response to Bureau of Drug Abuse Control requirements, conducts and contracts for studies on the medical aspects of drug abuse control.

c. Proposed Functional Statement, Director, BM

Acts as principal medical advisor to the Commissioner on all aspects of the Food and Drug Administration's responsibilities.

Develops Food and Drug Administration medical policy for approval of the Commissioner.

Plans the Bureau's medical program to support the Administration's responsibility in administering the various Acts and Regulations.

Maintains professional contacts with:

The Office of the Commissioner.
The Drug Industry.
The Professional and Trade Associations.
Other Governmental Agencies.

Provides executive direction of the Bureau's activities, supported by the Deputy Director, to accomplish its assigned mission.

d. Proposed Functional Statement, Deputy Director, BM

Directs and coordinates operating programs of the Bureau.

Coordinates Bureau operating programs with other HEW Department organizations.

Responsible for program operating decisions within policy framework of the Bureau.

Reviews program performance of subordinate organizations.

e. Proposed Functional Statement, Executive Officer, BM

Acts as principal advisor to the Director on all phases of management within the Bureau.

Plans and administers a Bureau system of planning, programming and budgeting.

Directs financial management of the Bureau's operations.

Manages the Bureau's personnel program within policies and guidelines established by the Office of the Commissioner and the Department.

Develops Administration and Bureau program and policy decisions into planning documents.

Collects, analyzes, and evaluates workload data.

Collects, analyzes, and evaluates program performance data.

Operates a general services program to support the Bureau in the areas of procurement, property, travel, space and facilities, communications, printing and reproduction, document and records management.

Establishes management and administrative guidelines for the Bureau.

Directs central document control and drug indexing activities.

f. Proposed Functional Statement, Assistant to the Director for Medical Resources and Liaison, BM

Represents the Bureau in liaison activities with the medical and scientific community.

Arranges for consultants, scientific committees, panels, and executive secretaries for committees.

Recommends to the Bureau Director the participation of Bureau personnel in professional meetings.

Determines need for and arranges for extramural clinical and scientific studies with universities or private organizations.

Provides medical library services to the Bureau of Medicine and other Bureaus of the Food and Drug Administration.

Provides statistical services and support to professional and management programs of the Bureau.

g. Proposed Functional Statement, Assistant to the Director for Industry Coordination, BM

Serves as the Bureau's central point of contact with the drug industry on:

Requirements for and application of new drug regulations;

Implications of proposed regulation change;

Status of pending new drug applications;

Reviews new drug status inquiries and determines if a formal application should be submitted.

Directs the Bureau's Field medical staff.

h. (This section deleted.)

i. Proposed Functional Statement, Assistant to the Director for Scientific Investigations, BM

Advises the Director concerning scientific investigation practices in the Bureau.

Assists the Bureau Director through conducting special studies and projects concerning current and proposed scientific investigative operations.

Develops recommendations and aids in the installation of new techniques designed to attain and maintain a high level of quality assurance in the Bureau's scientific investigations.

j. Proposed Functional Statement, Office of New Drugs, BM

Determines whether preclinical pharmacologic tests and other toxicological evaluations performed on new drug articles are adequate to support proposed clinical uses.

Determines whether clinical trials of new drugs on man are soundly conceived and are supported by prior animal testing and other controls adequate to justify the tests of man.

Determines whether applications by manufacturers for permission to market new drugs for general use should be approved on the basis of an evaluation of the evidence of safety and effectiveness.

Evaluates the truthfulness of claims for safety and effectiveness, and the adequacy of directions for uses, and warnings against misuses, appearing in proposed labeling; the adequacy of animal, clinical, and chemical tests performed on the new drug and the suitability of manufacturing and laboratory methods, facilities and controls exercised in factories producing new drugs.

k. Proposed Functional Statement, Associate Director for New Drugs, BM

Acts as principal advisor to the Director of the Bureau concerning the Bureaus' new drug activities.

Develops proposed medical policy of the Food and Drug Administration as to whether articles are to be considered as new drugs and require the submission of New Drug Applications.

Plans a program for adequate medical review of new drugs by professional personnel of varied disciplines.

Performs the final review of the recommendations made on the Division Director for a new drug and signs recommendations for the Bureau Director.

Establishes special priorities for new drug reviews.

Keeps abreast of scientific developments, pending legislative actions, and prepares long-range plans and programs to fulfill the Bureau's mission in reviewing new drugs.

l. Proposed Functional Statement, Deputy Associate Director for New Drugs, BM

Directs, with full authority from the Associate Director, the professional efforts of the Divisions, particularly as they involve the passage of drugs through the investigational phase, medical evaluation phase, and into the follow-up period.

Assigns priorities to new drug applications and determines the channels of review.

Monitors the review status system to determine the review status of NDA's and IND's; directs changes in priorities as required.

Details professional, technical, and clerical personnel between Divisions for short periods to accomplish peak work loads and special reviews.

Coordinates the review program with other areas of the Bureau of Medicine and other Bureaus of FDA.

m. Proposed Functional Statement, Administrative Office, Office of New Drugs, BM

Acts as principal advisor to the Associate Director on administrative activities.

Collects budgetary information from Divisions, summarizes the information for reviews by the Associate Director and forwards to the Bureau Director. Keeps the Associate Director informed as to the financial status of his programs.

Disseminates planning and program information received from the Office of the Bureau Director to Division Directors for action.

Serves as the focal point within the Office of New Drugs for all personnel programs and actions.

Provides the Associate Director and Division Directors with administrative services within the Office.

Maintains a system to provide the Deputy Associate Director of the Office of New Drugs with a status report of new drugs in the review process.

n. Proposed Functional Statement, Division of Cardiopulmonary and Renal Drugs, BM

The Division of Cardiopulmonary Renal Drugs performs all of the functions outlined in the overall functions for the Office of New Drugs with regard to drugs that will be classified cardiopulmonary renal drugs.

o. Proposed Functional Statement, Division of Neuropharmacological Drugs, BM

The Division of Neuropharmacological Drugs performs all of the functions outlined in the overall functions for the Office of New Drugs with regard to drugs that will be classified neuropharmacological drugs.

p. Proposed Functional Statement, Division of Dental and Surgical Adjuncts, BM

The Division of Dental and Surgical Adjuncts performs all of the functions outlined in the overall functions for the Office of New Drugs with regard to drugs that will be classified dental and surgical adjuncts.

q. Proposed Functional Statement, Division of Metabolism and Endocrine, BM

The Division of Metabolism and Endocrine performs all of the functions outlined in the overall functions for the Office of New Drugs with regard to drugs that will be classified metabolism and endocrine drugs.

r. Proposed Functional Statement, Division of Anti-Infective Drugs, BM

The Division of Anti-Infective Drugs performs all of the functions outlined in the overall functions for the Office of New Drugs with regard to drugs that will be classified anti-infective drugs.

s. Proposed Functional Statement, Division of Oncology and Radiopharmaceuticals, BM

The Division of Oncology and Radiopharmaceuticals performs all of the functions outlined in the overall functions for the Office of New Drugs with regard to drugs that will be classified oncology and radiopharmaceutical drugs.

t. Proposed Functional Statement, Office of Medical Review, BM

Provides assistance on medical matters to legal officers in hearings and court cases.

Reviews and evaluates promotional material for drugs, devices and books which are sold principally through the mails and after consideration of the drug's formula, design of the device, or review of the book, forward a report to the Chief Postal Inspector indicating whether or not there is a convincing medical basis for a fraud action.

In Post Office Fraud hearings gives medical testimony in support of the Department's charges of false and fraudulent claims, and when indicated, makes arrangements for other physicians to testify in support of the Government's position.

Testifies at Grand Jury hearings when requested by the Post Office Department and assists the U.S. Attorney by explaining the medical aspects of the particular case and assists him in preparation of the case for trial.

Advises the Post Office Department of the need or desirability for clinical studies to support actions against false and fraudulent therapeutic claims set forth in the Department's complaint, plans such studies, and secures the cooperation of physicians and scientists in carrying them through to completion.

Reviews advertising claims and promotional labeling and recommends actions to prevent misleading and false claims.

Develops medical facts and opinions to establish medical policy with respect to therapeutic devices and appliances having medical claims.

Provides necessary medical evidence and expert witnesses to support legal actions involving violative devices.

u. Proposed Functional Statement, Associate Director for Medical Review, BM

Acts as principal advisor to the Director of the Bureau on all Medical Review activities with special emphasis on developing and presenting medical data to support new drug hearings and legal actions.

Develops proposed medical policy of the Food and Drug Administration regarding drug advertising and therapeutic claims of devices and appliances.

Plans a program for adequate continuing medical review of drug advertising, promotional material and medical claims.

Performs final review of opinions and recommendations in support of hearings and legal actions and approves for the Bureau Director.

Establishes priorities for projects assigned to the Office.

Keeps abreast of scientific knowledge and developments, pending legislation action and prepares long-range plans and programs to fulfill the Bureau's mission of medical review of drugs and devices.

v. Proposed Functional Statement, Deputy Associate Director for Medical Review, BM

Directs, with full authority from the Associate Director, the professional efforts of the Divisions, particularly as they involve the preparation of medical facts and opinions to support hearings and legal actions.

Assigns priorities to develop facts and opinions to support hearings and legal actions.

Monitors the progress of the Divisions in developing medical review data.

w. Proposed Functional Statement, Drug Abuse Coordination Staff, BM

Performs staff work regarding pharmacology, clinical pharmacology, and adverse reaction evaluations about stimulant, depressant, or hallucinagenic drugs.

In response to Bureau of Drug Abuse Control and other program requirements, contracts for clinical pharmacology studies of stimulant and depressant drugs.

Answers inquiries and questions pertaining to drug abuse matters.

Represents the Food and Drug Administration in relationships with the Advisory Committee on the Abuse of Stimulant and Depressant Drugs and act as Executive Secretary of that Committee.

x. Proposed Functional Statement, Administrative Office, Office of Medical Review, BM

Acts as principal advisor to the Associate Director on administrative activities.

Collects budgetary information from Divisions, summarizes the information for review by the Associate Director and forwards to the Bureau Director. Keeps the Associate Director informed as to the financial status of his programs.

Disseminates planning and program information received from the Office of the Bureau Director to Division Directors for action.

Serves as the focal point within the Office of Medical Review for all personnel programs and actions.

Provides the Associate Director and Division Directors with administrative services within the Office.

y. Proposed Functional Statement, Division of Case Review, BM

Reviews proposed legal actions involving medical issues and recommends appropriate action on the basis of medical evidence.

Determines the necessity for field investigation of drug problems and when indicated, assists the field in making these investigations.

Directs, designs, or conducts clinical investigations to obtain the medical and other scientific facts necessary for the final determination of policy and to support regulatory actions on violative drugs.

Develops medical evidence, procures expert medical witnesses, and collaborates with the Bureau of Regulatory Compliance and the Office of the General Counsel to provide medical support in new drug hearings and court cases.

Provides technical advice to the General Counsel and to the U.S. Attorney in the presentation of court cases, including preparing and answering of interrogatories, depositions, and sitting with the attorneys in court to advise on cross-examination of opposition witnesses.

z. Proposed Functional Statement, Division of Medical Advertising, BM

Monitors and evaluates professional journal advertising, and promotional labeling and advertising contained in establishment inspection reports and submitted under the records and reports requirements.

Recommends regulatory procedures to deal with false or misleading claims in advertising and promotional labeling or failure of prescription drug advertisements to fairly present in brief summary, information concerning side effects, contraindications and effectiveness of drugs.

Cooperates with the Bureau of Regulatory Compliance and the Bureau of Education and Voluntary Compliance in furnishing and medical support for trade correspondence and regulatory proceedings based on the advertising and promotional labeling for prescription drugs.

aa Proposed Functional Statement, Division of Medical Devices, BM

Develops medical facts and opinions necessary to establish Food and Drug Administration medical policy with respect to therapeutic devices and appliances having medical claims.

Conducts or directs research, testing, and laboratory studies required to determine the technical adequacy, qualitative characteristics, physical characteristics, and the physical effects produced by medical devices and appliances.

Conducts or directs clinical studies to determine the truthfulness or falsity of claims made in the labeling of such devices.

In cooperation with the Bureau of Regulatory Compliance, provides necessary medical evidence and expert witnesses to support legal actions involving violative devices.

bb. Proposed Functional Statement, Office of Drug Surveillance, BM

Evaluates the safety and efficacy data and proposed labeling in supplements to new drug applications and makes appropriate recommendations to the Division Director with respect to approval and disapproval of the supplements.

Conducts containuing surveillance and medical evaluation of the labeling, clinical experience and reports of adverse reactions, including those submitted by an applicant under the records and reports requirements, of all drugs for which a new drug approval is in effect.

Determines whether there is a need for revised labeling, withdrawal of approval of the drug, or recall of the drug from the market.

Consults with medical experts to ascertain the consensus of informed medical opinion relating to current problems regarding individual or classes of drugs.

Reviews inspection and other findings designed to reveal whether new drugs are being marketed in accordance with commitments contained in new drug applications.

When the Office determines there is a need for labeling revision, withdrawal of a new drug approval or removal of a new drug from the market, makes appropriate recommendations to the Division Director.

Provides medical evaluation with regard to the safety of foods, particularly special dietary foods, food additives, and cosmetics.

Maintains a system to obtain reports of adverse reactions from the use of drugs.

Maintains a system to collect reports of and disseminate information on hazardous substances.

cc. Proposed Functional Statement, Associate Director for Surveillance, BM

Acts as principal advisor to the Director of the Bureau concerning the Bureau's responsibility for medical surveillance of drugs.

Develops proposed medical policy of the Food and Drug Administration for the surveillance of drugs being marketed through prescription and retail channels.

Plans a program for adequate surveillance, supplemental review, adverse reaction, and hazardous substances activities.

Performs the final review of proposed action documents and signs such recommendations for the Bureau Director.

Establishes special priorities for surveillance of particular drugs or groups of drugs.

Keeps abreast of scientific developments, pending legislative actions, and prepares long-range plans and programs to fulfill the Bureau's mission in drug surveillance.

dd. Proposed Functional Statement, Deputy Associate Director for Surveillance, BM

Directs, with full authority from the Associate Director, the professional efforts of the Divisions, particularly as they involve the processing of evaluation documents.

Assigns project priorities to Divisions and determines channel of surveillance evaluations.

Monitors a system of surveillance review and evaluation; directs changes in professional methodology as required.

ee. Proposed Functional Statement, Administrative Office, Office of Drug Surveillance, BM

Acts as principal advisor to the Associate Director on administrative activities.

Collects budgetary information from Divisions, summarizes the information for review by the Associate Director and forwards to the Bureau Director. Keeps the Associate Director informed as to the financial status of his programs.

Disseminates planning and program information received from the Office of the Bureau Director to Division Directors for action.

Serves as the focal point within the Office of Drug Surveillance for all personnel programs and actions.

Provides the Associate Director and Division Directors with administrative services within the office.

ff. Proposed Functional Statement, Division of Supplemental Review, BM

Evaluates the safety and efficacy data provided in supplements to new drug applications.

Evaluates proposed labeling changes submitted as part of supplements to new drug applications.

Monitors and otherwise refers to appropriate catalogs of labeling for all new drugs to assure that supplemental labeling changes are consistent with and otherwise in conformity with the labeling of similar or comparable drug articles.

Makes appropriate medical recommendations to the Office of Drug Surveillance with respect to approval or disapproval of supplements to new drug applications.

gg. Proposed Functional Statement, Division of Epidemiology, BM

Collects, evaluates, and disseminates information obtained with regard to the hazards of chemicals used in the household and of cosmetics, pesticides, food additives, and the accidental ingestion of drugs.

Develops precautionary statements for hazardous substances covered by Federal laws.

Makes recommendations for further study, precautionary labeling, changes in labeling, or withdrawal from use, to other Divisions in the Bureau of Medicine and the Office of the Bureau Director.

Conducts clinical studies based on hospital records keeping systems.

hh. Proposed Functional Statement, Division of Drug Monitoring, BM

Makes preliminary review and analysis of all adverse drug reactions coming into the Bureau of Medicine.

Administers the Hospital Adverse Drug Reaction Reporting Program and develops and coordinates other sources of adverse drug reaction information.

Receives, and disseminates information obtained from those sources.

Screens adverse reaction reports to initiate prompt in-depth evaluation by other Divisions of situations that may require changes in labeling, issuance of warning letters, withdrawal of new drug approvals, or removal of drugs from the market.

Makes in-depth evaluations when requested.

ii. Proposed Functional Statement, Division of Antibiotic and Insulin Certification, Bureau of Science

Jointly administers the antibiotic and insulin certification programs.

Assists Bureau of Medicine in the evaluation of the adequacy and reliability of chemical and biological data in proposals for listing for certification antibiotic and insulin drugs and dosage forms.

Assists Bureau of Medicine in the development of specifications, tests, and methods of assay for antibiotic and insulin drugs.

Assists Bureau of Medicine in the formulation of judgments on the nature of various antibiotic and insulin drugs including their safety and efficacy in use.

Conducts laboratory tests and assays of samples submitted for certification, including tests for identity, composition, potency, sterility, and pyrogenicity.

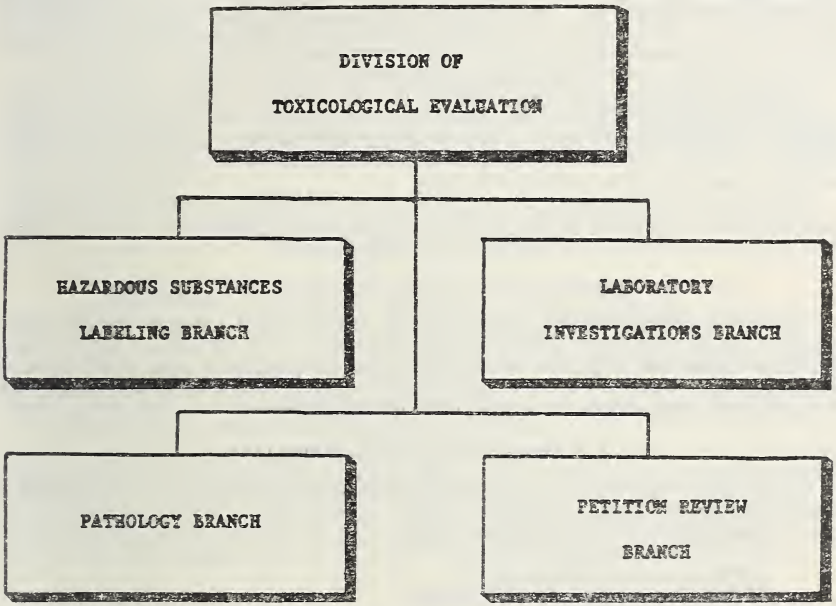
Conducts research programs to secure and organize new scientific information about the composition, properties, and interactions of these drugs to provide bases for the improvement of analytical methods and the development of sound opinions and policies.

Performs examinations and tests required to support regulatory programs involving these drugs.

Serves as a repository of expertise and information concerning antibiotic and insulin drugs.

Establishes planning, reporting, and accomplishment appraisal procedures.

jj. Proposed organizational structure, Division of Toxicological Evaluation, BS



kk. Proposed Functional Statement, Division of Toxicological Evaluation, BS

Evaluates scientifically pesticide and food additive petitions with respect to adequacy and reliability of toxicological data and tests.

Evaluates scientifically color additive petitions and proposals with respect to adequacy and reliability of toxicological data and tests.

Evaluates scientifically labeling for hazardous substances.

Plans and conducts appropriate laboratory investigations, such as—

Acute and chronic administration studies on various classes of pesticide chemicals, food additives, drugs, colors, and hazardous substances to provide bases for evaluation of new proposals, and bases for review of existing tolerances and uses.

Investigations to check data submitted by petitioners.

Studies in application and interpretation of new procedures.

Studies to detect likelihood of potentiation of mixtures of pesticide chemicals, additives, and drugs.

Serves as a repository of expertise and information on the toxicology of pesticide chemicals, food additives, color additives, drugs and hazardous substances.

Establishes planning, reporting, and accomplishment appraisal procedures.

C. Justification in Terms of Sound Organizations Criteria

The proposed organization for the Bureau of Medicine is in agreement with sound organization principles. Related work is grouped into practically administered units. Careful attention has been given to clearly identify responsibilities. Duplication of responsibilities has been minimized and has been built into the organization only where the benefits of separate review are considered to outweigh the apparent inefficiencies of duplicated effort.

Several more specific aspects of the soundness of the proposed organization are discussed below.

1. COORDINATION OF RELATED WORK

At present, the organization structure of the Bureau of Medicine requires that Investigational Drug Notices and New Drug Applications to be reviewed by different medical officers in separate branches. Thus, drug applications for the same drug are reviewed by two different groups of medical officers. Under the proposed organizational structure, both Investigational Drug Notices and New Drug Applications would be handled by the same group of medical officers.

Adverse reactions work now assigned to the Division of Medical Information and the supplement review work assigned to the Division of Medical Information would be consolidated in the Office of Drug Surveillance. This work is closely related. Proper review of proposed supplements often involves careful review of the adverse reactions received to date.

The many regulatory activities of the Bureau of Medicine would be coordinated in the Office of Medical Review. This involves the regulatory work involved in case review, medical advertising, and medical devices.

2. STRENGTHENING THE OFFICE OF THE BUREAU DIRECTOR

Executive direction of the Bureau will be strengthened through the establishment of appropriate staff offices within the Office of the Director. The Bureau Director will receive high level technical advice in specialized areas and increased administrative assistance, and the Bureau's medical and scientific staff will receive increased support from the Office of the Director.

3. EMPHASIS ON MEDICAL SPECIALTY

Recognition is given in the proposed organization for division of work in the new drug area by medical specialty, i.e.—

Cardiopulmonary and Renal Drugs.
Neuropharmacological Drugs.
Dental and Surgical Adjuncts.
Metabolism and Endocrine Drugs.
Anti-infective Drugs.
Oncology and Radiopharmaceuticals.

This will permit the designation of groups of medical officers to review IND's and NDA's by area of specialization. This will have the advantage of expediting review of drugs designed to treat particular types of illnesses. It will also enable FDA to fully utilize medical officers in their field of specialty and highest technical ability.

4. ESTABLISHMENT OF TEAM CONCEPT IN IND–NDA PROCESSING

Uniformity in and expediency of reviewing IND's and NDA's will be strengthened by the addition of chemists and pharmacologists to the Office of New Drugs. They will join the medical officers to function as teams. In a sense this will result in a one-stop operation in the review of IND's and NDA's. The process of coordinating the reviews of chemists, pharmacologists, and medical officers located in different buildings or separate offices will be eliminated.

D. Impact on Other Organizations

The proposed changes should have a favorable effect on the other organizations of FDA. The proposed new organization should have the effect of expediting Bureau action in the many areas of the Bureau's responsibilities. Internally, the Bureau should be more efficient, and with the transfer of several closely related functions from the Bureau of Science to the Bureau of Medicine, the entire Agency should be more effective.

The Bureaus which rely on the Bureau of Medicine for its expertise should be most noticably effected by the proposed change. The stronger and more efficient administrative organization of the Bureau should give the Bureau of Regulatory Compliance, the Bureau of Drug Abuse Control, and the Bureau of Science more responsive service to their requests for the special expertise of the Bureau of Medicine.

In general, the effect of the proposed organization on the other organizations of the Agency are expected to be favorable.

E. Budgetary and Staffing Implications

It is anticipated that the proposed changes will be accomplished within the context of existing personnel ceilings for the Bureau of Medicine and other effected units. As a result, we anticipate no increase above budgeted funding levels for the units concerned.

Part 3—Summary of Enforcement Activities by Division of Biologics Standards (NIH).

Department of Health, Education, and Welfare,
Public Health Service,
National Institutes of Health,
Bethesda, Md., February 23, 1966.

Mr. Daniel J. Manelli,
Special Subcommittee on Investigations, Committee on Interstate and Foreign Commerce, Rayburn House Office Building, Washington, D.C.

Dear Mr. Manelli: I am including herewith a short résumé of all legal actions which have been entered into in connection with the biological products control provisions of the Public Health Service Act.

Approximately four other cases are under study, but whether these will result in actual indictments will not be clear until the investigations have been completed.

Sincerely yours,

Roderick Murray, M.D.,
Director, Division of Biologics Standards.

RÉSUMÉ OF LEGAL ACTIONS, FEBRUARY 16, 1966

Kansas City, 1915	Plea of guilty for shipping a biological product without a license.
John P. Calise and Westchester Blood Service, Inc.	An 80-count indictment dated January 25, 1962, charging alteration of labels was brought against the defendants. Guilty plea.
Sidney Steinschreiber, et al.	In a 15-count indictment dated October 10, 1962, charging conspiracy to manufacture plasma (for human use) in an unlicensed establishment and also transporting the plasma from one state to another and to a foreign country, three defendants and two corporations were found guilty. The charges were dismissed against one defendant. Two defendants filed a petition for a writ of Certiorari to the Supreme Court. It was denied.
Paterson Blood Bank, Inc., et al.	An indictment of 36 counts dated July 10, 1963, including false labeling of blood for transfusion and interstate shipment for sale of blood that was processed in an unlicensed establishment was brought against the defendants. One of the three defendants and the corporation were found guilty of 31 counts. Stephan Lillo denied writ of Certiorari.
Robert P. Wittenstein and Servicio Internacional de Sangre, Inc.	An indictment of 14 counts dated July 28, 1964, charging false labeling, interstate shipment of Packed Red Blood Cells (Human) which were manufactured in an unlicensed establishment, and adulteration, under the FDA Act, was brought against the defendants. The trial is scheduled for March 1966.
J. J. Van Gasse, M.D. and Intermedic, Inc.	An 11-count Information was filed on April 12, 1965, against the defendants and the corporation charging them with interstate shipment for sale of an allergenic extract which had not been manufactured in a licensed establishment. A plea of guilty on all counts was made for the corporation.
Milton Luden and Luden Laboratories, Inc.	A 5-count Information was filed on June 7, 1965, against the defendant and corporation charging them with interstate shipment for sale of an allergenic extract which had not been manufactured in a licensed establishment. Defendant has entered a plea of nolo contendere.
Charles Blank, Maxine Blank, and Dallas Blood Bank, Inc.	A 27-count indictment was returned on September 21, 1965, charging the defendants with false labeling of biological products. The trial is scheduled for April 1966.
Krebiozen Research Foundation.	An inspector from this Division represented the Division of Biologics Standards in the investigation of this drug starting in February 1963. He was required to act as a Government witness on two occasions during the trial. This trial has ended with the acquittal of the defendants.
George S. Zuccala and Zuccala Research Laboratories.	George S. Zuccala was arrested on January 21, 1966, on a charge of illegal interstate shipment of a product subject to the Public Health Service Act. On bail and awaiting arraignment.

Appendix I

Part 1—Major Medical Information Resources in the United States

Among the nation's general medical libraries there are two in the Federal Government whose collection, size, subject breadth, and influence exercised through their services rank them as pre-eminent in the general field of medical information.

National Library of Medicine
8600 Wisconsin Avenue
Bethesda, Maryland 20014

Open to the public, the Library answers technical questions, assists in literature searches, and lends materials on an inter-library loan basis. It publishes the monthly *Index Medicus*, a listing of the world periodical literature of the biomedical sciences, which covers 150,000 items each year and is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402

Medical and General Reference Library
Veterans Administration
810 Vermont Avenue, N.W.
Washington, D.C. 20402
Telephone: 202–389–2678

Serves as an information clearinghouse for the VA Central Office and for VA hospitals and regional offices. Maintains two collections of books, pamphlets, and journals. One includes publications on medicine and related fields. The other pertains to personnel and public administration materials. Bibliographies are compiled and literature searches are made for VA staff. Services are available to Government agencies and for unique public requests.

Of the large number of outstanding non-Governmental general medical libraries, three must be included in any list of major medical information resources. Collectively these three organizations represent large banks of current, historical, and foreign literature in all forms as well as a wide variety of services to both the medical profession and the public.

American Medical Association
535 North Dearborn Street
Chicago, Illinois 60610
Telephone: 312–527–1500

Provides consulting, reference and document services and issues publications. Serves primarily physicians and members of the health professions. Provides general health information to the public. Literature searches and photocopying services are provided free of charge to physicians. Publications include: *Journal of the American Medical Association*, weekly: *Today's Health*, monthly; and *American Journal of Diseases of Children*, monthly.

New York Academy of Medicine
2 East 103rd Street
New York, New York 10029
Telephone: 212–876–8200

Maintains an extensive library of books, journals, pamphlets, and theses on medicine and its allied sciences in all languages. The library is open to the public, but services are primarily for physicians and scientists. Reference services are provided and photoduplication is offered for a fee. A file is maintained of freelance workers who can provide translations, bibliographies, and editorial assistance. Maintains a collection of portraits of physicians and a list of bibliographical sources.

College of Physicians of Philadelphia
19 South 22nd Street
Philadelphia, Pennsylvania 19103
Telephone: 215–563–6626.

Maintains an extensive library of medical and related literature, including both current and historical materials in all major languages. The library is open to the public without charge and reference service is provided. Sup-

ports a medical museum containing specimens, skulls, and surgical instruments of historical value. Provides a medical documentation service through the library. This includes literature scanning, preparing bibliographies, abstracts, and translations for a fee.

Within the Federal Government structure there are five major specialized medical information activities whose collections and services are primarily oriented toward specific agency mission responsibilities. The importance of these subject specialties and the significance of the information available, require that they be ranked as major resources for medical information.

Mr. J. Stewart Hunter, Chief
Information and Publications
Office of the Surgeon General
Department of Health, Education, and Welfare
333 Independence Avenue, S.W.
Washington, D.C. 20203

Directs inquiries to all units of the Public Health Service including the Bureau of State Services and the National Institutes of Health.

Division of Public Information
Food and Drug Administration
U.S. Department of Health, Education, and Welfare
Washington, D.C. 20201

Collects and disseminates information of all kinds relating to the programs and mission of the agency. Public inquiries are answered and new publications are developed to cover major topics of consumer interest. Inquiries concerning current research in the Food and Drug Administration should be addressed to: Bureau of Biological and Physical Sciences, Food and Drug Administration, D.C. 20201.

Aerospace Medical Division (AMA)
Air Force Systems Command
U.S. Department of the Air Force
Brooks Air Force Base, Texas 78236

Provides information concerning the current research programs conducted by the Division. Inquiries regarding specific phases of the program or work of the individual laboratories may be addressed directly to any of the seven organizational units at the following addresses. 1) School of Aerospace Medicine, Brooks AFB, Tex.; 2) Arctic Aeromedical Laboratory, Fort Jonathan M. Wainwright, Alaska; 3) Aerospace Medical Research Laboratories, Wright-Patterson Air Force Base, Ohio; 4) Aeromedical Research Laboratory, Holloman Air Force Base, N. Mex.; 5) Personnel Research Laboratory, Lackland Air Force Base, Tex.; 6) USAF Hospital, Lackland Air Force Base, Tex.; and 7) Epidemiological Laboratory, Lackland Air Force Base, Tex.

Medical Research and Development Command
Office of the Surgeon General
U.S. Department of the Army
Washington, D.C. 20012

Directs the Army medical research and development program and advises on the availability of information from its field stations and installations. These include: 1) Walter Reed Army Institute of Research, Washington, D.C.; 2) U.S. Army Prosthetics Research Laboratory, Walter Reed Medical Center, Washington, D.C.; 3) U.S. Army Medical Unit, Fort Detrick, Md.; 4) U.S. Army Medical Research Laboratory, Fort Knox, Ky.; 5) U.S. Army Medical Research and Nutrition Laboratory, Fitzsimons General Hospital, Denver, Colo.; 6) U.S. Army Surgical Research Unit, Brooke Army Medical Center, Fort Sam Houston, Tex.; and 8) Medical Equipment Development Laboratory, Fort Totten, N.Y.

Chief, Bureau of Medicine and Surgery
Department of the Navy
Washington, D.C. 20390

Provides information concerning the current research programs conducted at the Bureau's installations which include: 1) National Naval Medical Center, Bethesda, Md.; 2) U.S. Naval Aviation Medical Center, Pensacola, Fla.; 3) Naval Medical Field Research Laboratory, Camp Lejeune, N.C.; and 4) Naval Medical Research Laboratory, New London, Conn.

In the non-Federal section, there are many specialized medical information activities which offer significant contributions to the medical world and the public. Three of these, however, because they cover important specialties, deserve pre-eminent rank.

American Hospital Association
840 North Lake Shore Drive
Chicago, Illinois 60611
Telephone: 312–944–4350

Provides information, advice, and assistance on specific problems. Consulting services are for member institutions only. Publications include: *Hospital Literature Index*, quarterly; *Hospitals*, semimonthly; and *Hospital Planning Abstract Service*, 6 times a year.

American Pharmaceutical Association
2215 Constitution Avenue, N.W.
Washington, D.C. 20007
Telephone: 202–628–4410

Consulting and document services are available mainly to pharmacists, others on a need-to-know basis. Publications include: *Journal of the American Pharmaceutical Association*, monthly; *Journal of Pharmaceutical Sciences*, monthly; and the *National Formulary*, every five years.

American Dental Association
222 East Superior Street
Chicago, Illinois 60611
Telephone: 312–944–6730

Provides consulting, reference and referral services. Interlibrary loan and photoduplication services also available. Services are provided free of charge to members of the Association, dentists, dental technicians, nurses and students. Others as time permits. Publications include: *Index to Dental Literature*, quarterly; *Dental Abstracts*, monthly; and the *Journal of the American Dental Association*, monthly.

There exist several major information services supported by the Federal government which, although they do not specialize in medical information, contain medical and related interdisciplinary information of significant value. Although not medical libraries, they offer so much medical information and so many services of various types as to require their inclusion in a list of major medical information activities.

Science Information Exchange
209 Madison National Bank Building
1730 M Street, N.W.
Washington, D.C. 20036

The SIE is a clearinghouse for research in progress in the life and physical sciences. Questions are answered by a staff of scientists. Services are provided without charge to research investigators and administrators associated with recognized research institutions.

Scientific and Technical Information Division (Code ATSS)
National Aeronautics and Space Administration
Washington, D.C. 20546

This Division provides a central service for the dissemination of scientific and technical reports dealing with aeronautics and space to Government agencies, their contractors and grantees, and other participants in the national space program. The Division also answers specific inquiries, performs literature searches, and prepares bibliographies. Among its publications is the semimonthly abstract journal *Scientific and Technical Aerospace Reports*, available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Division of Technical Information Extension
U.S. Atomic Energy Commission
P.O. Box 62, Oak Ridge
Tennessee 37831

The DTIE is responsible for the acquisition, organization, reproduction, and the dissemination of scientific information in support of AEC research and development, civilian application, weapons, international cooperation, and educational assistance programs. The semimonthly *Nuclear Science Abstracts*, published by the AEC, is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

One non-Governmental counterpart to the above list is the following:

The John Crerar Library
35 West 33rd Street
Chicago, Illinois 60616

This Library, which is open to the public, maintains comprehensive English and foreign language collections in the physical and biological sciences and their applications in engineering, medicine, and agriculture and provides on-site reference service. Bibliographical searches, abstracting, current reporting and prior art searches are performed on a fee basis. Photocopies of library owned materials are available. Translating services as well as copies of translated technical material from the Special Libraries Association Translation Center are also available for a fee. Its publications include *Crerar Metals Abstracts* and *Leukemia Abstracts*.

A unique and very important medical information resource is the publication *Excerpta Medica* which, in 20 sections, covers all aspects of medicine. It is universally recognized as an authoritative source of medical information and therefore at least deserves mention among the top medical information resources. The complete address is as follows:

Excerpta Medica Foundation
2 East 103rd Street
New York, New York 10029

INTERNATIONAL SOURCE

The scientific community now has a registry of current worldwide research available at Geneva. There, the World Health Organization has established a Biomedical Research Information Service, and is beginning the huge task of building up its files by sending questionnaires to investigators in the life sciences all over the globe. Then it plans to begin disseminating information to individual scientists and to university, governmental, and industrial research organizations. The hope is to gather preliminary findings on a wide spectrum of research even before the results of continuing studies have been published in the various scientific journals.

World Health Organization
Rome, Italy

Part 2.—Biomedical Information Sources

Department of Health, Education, and Welfare

Air Pollution Technical Information Center, Division of Air Pollution, Bureau of State Services, Public Health Service, Washington, D.C. 20201.
Arctic Health Research Center, Bureau of State Services, Public Health Service, 945 Sixth Avenue (Box 960), Anchorage, Alaska 99501.
Cancer Chemotherapy National Service Center, NCI–NIH, Bethesda, Maryland.
Cancer Control Branch, Division of Chronic Diseases, Bureau of State Serivces, Public Health Service, Washington, D.C. 20201.
Cancer Information Center, Scientific and Technical Information Office, National Cancer Institute, NIH, Bethesda, Maryland 20014.
Clearinghouse for Research in Child Life, Children's Bureau, Welfare Administration, DHEW, Room 2616 Tempo R Bldg., 4th and Independence Avenue, S.W., Washington, D.C.
Committee on Thrombolytic Agents, Extramural Programs, NHI–NIH, Bethesda, Maryland 20014.
Communicable Disease Center, Atlanta, Georgia 30333.
Dental Care Economics Clearinghouse, Division of Dental Public Health and Resources, 8120 Woodmont Building, Bethesda, Maryland 20014.
Dental Health Center, San Francisco, California.
Food and Drug Administration, Washington, D.C.
Drug Addiction Center, Public Health Service, DHEW, Lexington, Kentucky.
Fluoridation Services, Public Health Service, Woodmont Building, Room 508, Bethesda, Maryland 20014.

Gallaudet College, Speech and Hearing Literature Project, Washington, D.C.
Health Communications Branch, Division of Community Health Services, Bureau of State Services, Public Health Service, Washington, D.C. 20201.
Health Manpower Branch, Division of Public Health Methods, Public Health Service, Washington, D.C. 20201.
Indian Health Information Center, Bureau of Medical Services, Public Health Service, Washington, D.C.
Information Exchange Groups (7), Office of Research Analysis and Evaluation, Division of Research Grants, NIH, Bethesda, Maryland 20014.
Migrant Health Branch, Division of Community Health Services, Public Health Service, Washington, D.C. 20201.
National Center for Health Statistics, Public Health Service, DHEW, Washington, D.C. 20201.
National Clearinghouse for Mental Health Information, National Institute of Mental Health, NIH, Bethesda, Maryland 20014.
National Clearinghouse for Poison Control Centers, Public Health Service, DHEW, 4th and C Street, S.W., Washington, D.C. 20201.
National Clearinghouse for Smoking and Health, Division of Chronic Diseases, Public Health Service, Washington, D.C. 20201.
NIH Library, Division of Research Services, NIH, Bethesda, Maryland 20014.
National Library of Medicine, 8600 Wisconsin Avenue, Bethesda, Maryland 20014.
PHS Medical Audiovisual Facility, Communicable Disease Center, Atlanta, Georgia 30333.
Nursing Homes and Related Facilities Branch, Division of Chronic Diseases, Public Health Service, Washington, D.C. 20201.
Nursing Research Information Center, Division of Nursing, Bureau of State Services, Public Health Service, Washington, D.C. 20201.
Office of Pesticides, Bureau of State Services—Environmental Health, Public Health Service, Communicable Disease Center, Atlanta, Georgia 30333.
Office of Scientific Communications, Division of Biologics Standards, NIH, Bethesda, Maryland 20014.
Psychopharmacology Service Center (absorbed in NIMH), NIH, Bethesda, Maryland 20014.
Quarantine Information Center, Division of Foreign Quarantine, Bureau of Medical Services, Public Health Service, DHEW, Washington, D.C.
Radiation Surveillance Center, Division of Radiological Health, Bureau of State Services, Public Health Service, Washington, D.C. 20201.
Regional Rehabilitation Research and Training Center in Mental Retardation, 2410 San Antonio Street, Austin, Texas 78705.
Research Documentation Section, Statistics and Analysis Branch, Division of Research Grants, NIH, Bethesda, Maryland 20014.
Scientific and Technical Communications Officer, National Institute of Allergy and Infectious Diseases, NIH, Bethesda, Maryland 20014.
Scientific and Technical Communications Officer, National Institute of Arthritis and Metabolic Diseases, NIH, Bethesda, Maryland 20014.
Scientific and Technical Communications Officer, National Institute of Child Health and Human Development, NIH, Bethesda, Maryland 20014.
Scientific and Technical Communications Officer, National Institute of Dental Research, NIH, Bethesda, Maryland 20014.
Scientific and Technical Communications Officer, National Institute of General Medical Sciences, NIH, Bethesda, Maryland 20014.
Scientific and Technical Communications Officer, National Heart Institute, NIH, Bethesda, Maryland 20014.
Scientific and Technical Information Resources Branch, Division of Research Facilities and Resources, NIH, Bethesda, Maryland 20014.
Special Virus Leukemia Program, Scientific and Technical Information Office, National Cancer Institute, NIH, Bethesda, Maryland 20014.
Technical Information Section, Division of Occupational Health, Public Health Service, 1014 Broadway, Cincinnati, Ohio 45202.
Technical Information Section, Neurological and Sensory Disease Service Program, Division of Chronic Diseases, Public Health Service, Washington, D.C. 20201.

Part 3—Biomedical Information Sources—Recipients of DHEW Support (Current or Past)

Aerophysics Research Foundation, Santa Barbara Airport, Goleta, California.
Air Pollution Control Association, 4400 Fifth Avenue, Pittsburgh, Pa.
The American Foundation for Tropical Medicine, 551 5th Avenue, New York 17, New York.
American Psychiatric Association, 1700 18th Street, N.W., Washington, D.C.
American Psychological Association, 1200 17th Street, N.W., Washington, D.C.
Arthropod-Borne Virus Information Exchange, School of Public Health, University of California, Berkeley 4, California.
Association of American Medical Colleges, 2530 Ridge Avenue, Evanston, Illinois.
Audiovisual Method for Air Pollution Information, The Airlie Center, George Washington University, Box 341, Warrenton, Virginia.
Bay Area Air Pollution Control District, 1480 Mission Street, San Francisco 3, California.
Biological Serial Record Center, 2000 P Street, N.W., Washington, D.C. 20036.
Biological Studies of Psychotic Disorders, New York University Medical Center, New York, N.Y.
Brain Information Service, University of California, Los Angeles, Los Angeles, California.
Cardiovascular Epidemiology Clearinghouse, University of Michigan School of Public Health, Ann Arbor, Michigan.
Cardiovascular Literature Project, American University, 2000 G Street, N.W., Washington, D.C.
Center for Research in Careers, Harvard University Medical School, Boston, Massachusetts.
Central Registry for Cerebral Insufficiency, Baylor University, Houston, Texas.
Cerebrovascular Diseases Center, Mayo Clinic, Rochester, Minnesota.
Charlotte Drake Cardeza Foundation for Hematologic Research, Jefferson Medical College, Philadelphia, Pa.
Child Amputee Prosthetics Project, University of California, 10975 Wilshire Boulevard, Los Angeles, California 90024.
The Child Research Council, 4200 East Ninth Avenue, Denver, Colorado.
Center of Alcohol Studies, Rutgers-The State University, Box 560–73 Easton Avenue New Brunswick, New Jersey.
Clearinghouse for Information Related to Computer Application in Nutrition and Food Service Management, Medical Dietetic Program, Department of Preventive Medicine, The Ohio State University, 410 West 10th Avenue, Columbus, Ohio 43210.
Codification and Retrieval of Survey Data, Indiana University, Bloomington, Indiana.
Commission of Professional and Hospital Activities, Inc., 210 First National Building, Ann Arbor, Michigan.
Committee on Prosthetics Research & Development, National Academy of Sciences-National Research Council, 2101 Constitution Avenue, Washington, D.C. 20418.
Danish Cancer Registry, National Anti-Cancer League, Strandboulevad 49, København, Denmark.
Dental Research Information Center, American Dental Association, 211 East Chicago Avenue, Chicago, Illinois 60610.
Diabetes Literature Retrieval Project, University of Minnesota, Minneapolis, Minnesota.
Drosophila Information Service, University of Oregon, Eugene, Oregon.
Facility for Health Sciences Documentation Research, Western Reserve University, 10831 Magnolia Drive, Cleveland 6, Ohio.
Food Protection Committee, National Academy of Sciences-National Research Council, 2101 Constitution Avenue, Washington, D.C.
Foundation for Psychiatry, Mt. Kisco, New York.
Genetics Registry and Cardiovascular Study Unit, University of Utah College of Medicine, Salt Lake City, Utah.
Harvard Medlars Center, Harvard University, Boston, Massachusetts.
Hearing, Speech, Language, and Human Communication Center, Johns Hopkins University, Baltimore, Maryland.
Hormones, Adaptive Behavior and Psychiatry, Stanford University School of Medicine, Stanford, California.

Human Learning Laboratory & Research Center, University of Wisconsin, Madison, Wisconsin.
Information Processing in Living Systems, University of Michigan, Ann Arbor, Michigan.
Information Retrieval in the Visual Sciences, University of Chicago, 950 East 59th Street, Chicago, Illinois.
Insect Disease Diagnostic Service, Division of Invertebrate Pathology, 207 Agriculture Hall, University of California, Berkeley 4, California.
Institute for Advancement of Medical Communication, 341 Market Street, Philadelphia, Pennsylvania.
Institute for Health Sciences, Brown University, Providence, R.I.
Institute for Research in Vision, Ohio State University, Columbus, Ohio.
Institute of Agricultural Medicine, College of Medicine, State University of Iowa, Iowa City, Iowa.
Institute of International Medicine, University of Maryland School of Medicine Baltimore, Maryland 21201.
International Brain Research Organization, Secretariat, IBRO–UNESCO, Place de Fontenoy, Paris 7e, France.
International Reference Center for Immunoglobulins, WHO, Institute Biochemie, Lausanne, Switzerland.
The Kettering Laboratory in the Department of Preventive Medicine and Industrial Research, College of Medicine, University of Cincinnati, Cincinnati, Ohio.
Laboratory of Human Development, Stanford University, Stanford, California.
Leonard Wood Memorial for the Eradication of Leprosy, 79 Madison Avenue, New York, New York.
Mental Health Data Collector Service, South Carolina State Hospital, Columbia, South Carolina.
Mental Health Film Board, 164 East 38th Street, New York, 16 New York.
Mental Health Research Institute, University of Michigan, Ann Arbor, Michigan.
National Child Research Center, Washington, D.C.
National Cleft Lip and Palate Intelligence Center, San Francisco, California.
National Council on Crime and Delinquency, 44 East 23rd Street, New York, New York 10010.
Neurological Data Project, Massachusetts General Hospital, Boston, Massachusetts.
Neurosciences Research Information Center, Brookline, Massachusetts.
New York City. Office of Radiation Control, 386 Park Avenue South, New York, New York 10016.
Nutritional Requirements of Vertebrates Useful to Man, National Academy of Sciences—National Research Council, 2101 Constitution Avenue, Washington, D.C. 20418.
Oribatid Mites, Zoological Institute, University of Vienna, Vienna, Austria.
Parasitic Mites, R. W. Strandtmann, Department of Biology, Texas Technological College, Lubbock, Texas.
Parkinson Information and Research Center, Medical Library, Columbia-Presbyterial Medical Center, New York, N.Y.
Poisonous Plants, K. F. Lampe, University of Miami, Coral Gables, Florida.
Primate Information Center, Regional Primate Research Center at the University of Washington, Seattle, Washington 98015.
Psychiatric Disorder and Sociocultural Environment, Cornell University, Ithaca, New York.
Psychiatric Epidemiology Center and Field Stations, Columbia University School of Medicine, New York, New York.
Psychophysiology of Psychosomatic Disorders, Cornell Medical College, New York, New York.
Psychosomatic Clinical Research Center, Michael Reese Hospital, Chicago, Illinois.
Regional Center for the Study of Aging, Duke University Council on Gerontology, Duke University, Duke University Road, West Campus, Durham, North Carolina.
Regional Primate, Research Center and Primate Laboratory, University of Wisconsin, 1223 Capital Center, Madison, Wisconsin 53715.
Remediation of Disturbed and Retarded Children, University of Illinois, Urbana, Illinois.
Research Center for Early Childhood Schizophrenia, Indiana University School of Medicine, Indianapolis, Indiana.

Research Program in Quantitative Psychiatry, University of North Carolina, Chapel Hill, N.C.
Rockland Mental Disease Clinical Research Center, Rockland State Hospital, Orangeburg, N.Y.
Simpson Memorial Institute for Medical Research, University of Michigan, Ann Arbor, Michigan.
Society for Research in Child Development, Purdue University, Lafayette, Indiana.
Sociobehavioral Study Center for Mental Retardation, Pacific State Hospital, Pomona, California.
Spray Literature, Professor Kalman J. DeJuhasz, 423 West Park Avenue, State College, Pa. 16801.
State Information System for Health Facilities Planning, State of California, Department of Public Health, Berkeley, California.
Studies on Comparative Psycholinguistics, University of Illinois, Urbana, Illinois.
Suicide Prevention Center, 2521 West Pico Boulevard, Los Angeles, California 90006.
Systematic Bacteriology Research Group, Iowa State University, Ames, Iowa.
Trematode Diseases, Dr. George Anastos, Department of Zoology, University of Maryland, College Park, Maryland.
University of Alabama Medlars Center, 1919 7th Avenue South, Birmingham, Alabama 35233.
UCLA Medlars Center, University of California, Los Angeles, Los Angeles, California.
University of Colorado Medlars Center, Denver, Colorado.
University of Michigan Medlars Center, University of Michigan, Ann Arbor, Michigan.
Viral and Rickettsial Registry, American Type Culture Collection, Rockville, Maryland.
Vision and Visual Disorders Center, Harvard Medical School Library, Boston, Massachusetts.
World Federation for Mental Health, 1, Rue Gevray, Geneva, Switzerland.
Yerkes Regional Primate Research Center, Emory University, Atlanta, Georgia 30322

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